

Spirometry in the Occupational Health Setting—2011 Update

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Spirometry, the most frequently performed pulmonary function test (PFT), is the cornerstone of occupational respiratory evaluation programs. In the occupational health setting, spirometry plays a critical role in the primary, secondary, and tertiary prevention of workplace-related lung disease.¹ Used for both screening and clinical evaluations, spirometry tests are performed in a variety of venues ranging from small clinical practices to large testing facilities and multiple plant medical departments within an industry. Physicians and other health care professionals may conduct spirometry tests themselves or supervise others conducting the tests, or they may be involved only in interpreting test results. Whatever their level of involvement in the actual testing, spirometry users need to be aware that spirometry differs from many other medical measurements, since it depends on multiple factors for its results to be valid. If any of these factors malfunction, for example, if subject effort is flawed, equipment is not accurate, or technicians fail to elicit maximal cooperation and effort, results can be falsely *elevated* or *reduced*. These problems may profoundly impact conclusions that are drawn about a worker's pulmonary function, and will likely render the interpretations incorrect.

Recognizing the central role of spirometry in workplace respiratory programs, the American College of Occupational and Environmental Medicine (ACOEM) developed two spirometry position statements in the past decade which summarize advances of particular relevance to occupational health practice.^{1,2} However, since these statements were published, several important changes have occurred in the field of pulmonary function testing that significantly affect occupational spirometry testing. First, the American Thoracic Society (ATS) and the European Respiratory Society (ERS) issued a series of joint

official statements on standardization of lung function testing.³⁻⁵ Second, the International Organization for Standardization (ISO) issued a standard, ISO 26782, covering essential technical operating characteristics of spirometers.⁶ Third, the impact of real-world spirometry errors caused by improper use of some flow-type spirometers was documented and published.⁷ And fourth, attention has been increasingly paid to the interpretation of change in lung function over time.⁸⁻¹¹ To incorporate these important pulmonary function-testing changes into its recommendations, ACOEM has developed this 2011 update. The goal of this statement is to provide useful current information for all users of spirometry test results, from those who perform or supervise testing to those who only interpret or review results. The document is presented in a manner that allows those with specific interests to review those sections that are relevant to them. Four major topics are covered in this statement: (1) equipment performance, (2) conducting tests, (3) comparing results with reference values, and (4) evaluating results over time. To meet the varying needs of all spirometry users, Table 1 outlines the statement so that readers can turn immediately to sections that are most applicable to their interests. To assist readers in understanding the material, particularly in Sections 1 and 2, Fig. 1 presents spirometry from a valid test to compare with the flawed test results shown in Fig. 2 to 12 as discussed later.

EQUIPMENT PERFORMANCE

Since spirometers are not certified by the Occupational Safety and Health Administration (OSHA) or the National Institute for Occupational Safety and Health (NIOSH), health care professionals need to be aware of the four elements that contribute to accurate spirometer performance: (1) ATS/ERS and ISO recommend minimum performance-based standards for spirometers of all types; (2) prototype spirometers and their software undergo validation testing, preferably by an independent testing laboratory, to demonstrate that they meet these specifications; (3) spirometer users perform daily accuracy checks of the spirometer calibration so that defective spirometers can be removed from service until they are repaired; and (4) if sensor errors develop during subject testing, users need to recognize the errors and delete the resulting invalid tests even if not labeled as errors by the spirometer's software.

The American College of Occupational and Environmental Medicine recommends that facilities performing occupational spirometry tests maintain a procedure manual documenting the details of equipment type, spirometer configuration, manufacturer's guidelines, calibration log, service and repair records, personnel training, and standard operating procedures. Such a manual will permit troubleshooting if problems with anomalous test results arise.

Spirometer Specifications

In 2009, ISO issued specifications for technical aspects of spirometer performance, and many ISO requirements are identical to the 2005 ATS/ERS specifications. However, while the ISO standard focuses exclusively on spirometer performance, ATS/ERS provides additional important recommendations on the need for real-time displays to permit effective technician coaching and on user protocols for performing daily checks of spirometer accuracy. When ATS/ERS makes recommendations on spirometer design or calibration check protocols that are not addressed in the ISO standard, occupational spirometry users are advised to follow ATS/ERS guidelines. This particularly applies to the need for real-time graphical displays in the occupational health setting.

In 2005, the ATS/ERS restated, but did not change, its minimal performance-based recommendations for spirometer operating characteristics, including accuracy, precision, resistance and back pressure, and hard-copy graph size.⁴ However, for the first time, ATS/ERS also explicitly recommended that both flow-volume and volume-time curves of sufficient size be made available as tests are performed to enable effective coaching during the maneuver. In addition to a minimum instrument display size, ATS/ERS also recommended a standard spirometer electronic output, so that complete test results are saved and tracings can later be reconstructed electronically. The American Thoracic Society/European Respiratory Society minimum recommended display and hard copy graph sizes, which also comply with the ISO recommended graph aspect ratios, are shown in the Appendix.

The American College of Occupational and Environmental Medicine strongly recommends that spirometers used for occupational spirometry tests provide: (1) a real-time display of both flow-volume and

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TABLE 1. Spirometry in the Occupational Setting—2011 Update Topics

Equipment Performance
Spirometer specifications
Validation testing of spirometers
Spirometer accuracy checks
Avoiding sensor errors during subject tests
Conducting Tests
Technician training
Conducting the test
Testing goal for a valid test
Reporting results
Quality assurance reviews
Comparing Results With Reference Values
Reference values
Race adjustment of predicted values and LLNs
Interpretation algorithm
Evaluating Results Over Time
Longitudinal interpretation
Pre- to post-bronchodilator changes in pulmonary function
LLN, lower limits of normal

volume-time curves which meets or exceeds ATS/ERS minimum size and ISO minimum aspect ratio standards; (2) graphs in hard-copy printouts that meet or exceed ATS/ERS minimum size standards; and (3) standard electronic spirometer output of results and curves.

Beyond meeting these ATS/ERS minimum recommendations and ISO minimum requirements, ACOEM also recommends that spirometers used for occupational spirometry tests (1) save all information from up to eight maneuvers in a subject test session; (2) permit later editing and deletion of earlier flawed test results; (3) provide a complete spirometry test report for review of technical quality, which includes all flow-volume and volume-time

curves, and test results from at least the 3 best maneuvers, and preferably from all saved efforts; (4) optionally provide a separate final spirometry summary report for interpretation of the best test results; (5) provide computer-derived technical quality indicators; (6) provide a dedicated routine for verifying spirometer calibration; and (7) save indefinitely a comprehensive electronic record of all calibration and calibration verification results. These ACOEM and ATS/ERS recommendations and ISO requirements apply to both volume- and flow-type spirometers.

Validation Testing of Spirometers

The ATS/ERS 2005 statement and the 2009 ISO 26782 Standard⁶ include waveforms for validation testing of spirometers. Manufacturers submit a prototype spirometer and software for validation testing, which is preferably administered by an independent testing laboratory, or sometimes by the manufacturer. A letter or certificate is generated if the spirometer passes the testing. In addition to passing validation testing of a spirometer's operating characteristics, users in the occupational setting also need to determine whether the spirometer meets ATS/ERS specifications of adequate real-time displays and hard-copy graphs, and standard spirometer electronic output⁴ (see the Appendix).

If spirometers are purchased for use in the occupational health setting, ACOEM strongly recommends that (1) the manufacturer needs to provide written verification that the spirometer successfully passed its validation testing, preferably conducted by an independent testing laboratory, and that the tested spirometer and software version correspond with the model and software version being purchased; and (2) the spirometer needs to meet the ATS/ERS recommended minimum real-time display and hard-copy graph sizes for flow-volume and volume-

time curves and ISO minimum aspect ratios for these displays, as well as providing a standard spirometer electronic output (see the Appendix).

Spirometer Accuracy Checks

The 2005 ATS/ERS Spirometry Statement recommends that the accuracy of both volume- and flow-type spirometers is checked at least daily when a spirometer is in use. The acceptable spirometer response to a standard 3-L calibration syringe injection has been expanded to $\pm 3.5\%$ of the injected volume, or 2.90 to 3.10 L.⁴

Flow-type spirometer calibration is checked by injecting the 3-L calibration syringe at three different speeds to verify spirometer accuracy as varying flow rates enter the spirometer.⁴ The American Thoracic Society/European Respiratory Society-recommended injection speeds are approximately 6 L/s, 1 L/s, and 0.5 L/s, produced by injecting 3 L over approximately 0.5, 3, and 6 or more seconds. An acceptable spirometer response to each injection is a value between 2.90 and 3.10 L. If disposable sensors are used, it is recommended that a new sensor be drawn from the patient supply each time the calibration is checked. This frequent sampling and evaluation of sensors used for subject testing will help prevent erroneous subject test results caused by deteriorating accuracy of the sensor supplies over time.

Volume spirometers are checked for leaks daily and each time a breathing hose is changed (leaks are acceptable if they are smaller than 30 mL/min), as well as for the response to a single injection of a 3-L calibration syringe. Quarterly checks of volume spirometer linearity are also recommended by ATS/ERS.

Calibration syringes are checked for leakage on a monthly basis.⁴ Syringes are recalibrated periodically by the manufacturer using a method traceable to the National Institute of Standards and Technology. Recalibration is also needed whenever the syringe stops or becomes loose. Syringes are stored near the spirometer so that both are stored and used under the same environmental conditions.

Before performing accuracy checks, spirometer users need to determine whether a 3-L syringe injection simply verifies the spirometer's accuracy or whether, in fact, it resets the spirometer's calibration. Many currently available spirometers permit users only to check the calibration; that is, the calibration itself cannot be altered. However, some spirometers' settings are changed when a calibration syringe is injected, and other spirometers' settings are automatically changed if the spirometer fails to pass its accuracy check. When altering the calibration,

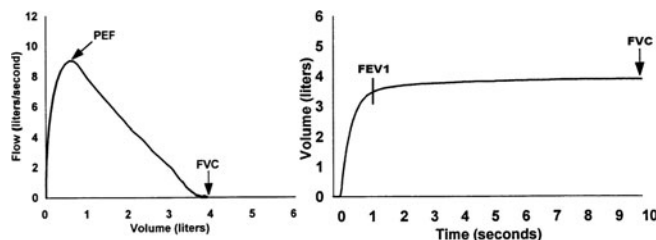


FIGURE 1. Valid test. Flow-volume curve (left) emphasizes start of test, rising immediately to a sharp peak and smoothly descending to zero flow. Volume-time curve (right) emphasizes end of test, initially rising rapidly, and then gradually flattening out and reaching 1 second of no visible volume change, at the FVC plateau. To permit effective subject coaching, the American Thoracic Society/European Respiratory Society recommends using spirometers that show both graphical displays as the test is performed and in sufficient size to clearly reveal technical errors.

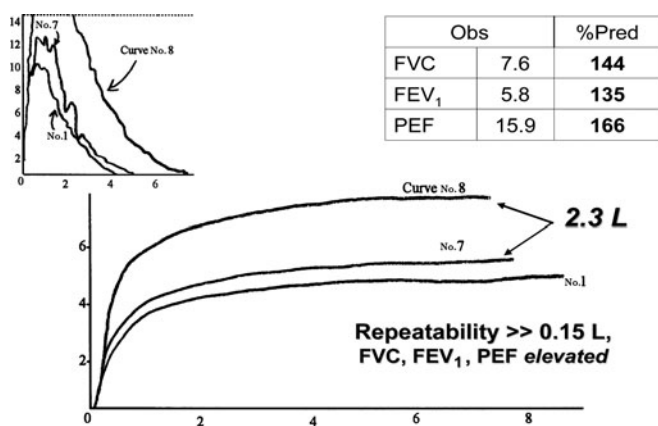


FIGURE 2. Sensor contaminated or blocked (by condensation, mucus, or fingers). Test results will be falsely increased and invalid and may produce erroneously “normal” automated interpretations. This problem often causes FVC and FEV1 repeatability to exceed 0.50 L, as values increase with each successive test, and the percentage of predicted values may also be unrealistically elevated. The entire test must be deleted and the sensor replaced if it becomes contaminated during a test. Reprinted with permission from Townsend et al.⁷

users need to carefully follow manufacturer instructions and then check the spirometer’s accuracy using a different routine and following the instructions outlined earlier.

The American College of Occupational and Environmental Medicine strongly endorses daily performance of accuracy checks when spirometers are in use, as recommended by ATS/ERS. The American College of Occupational and Environmental Medicine recommends saving calibration tracings and records *indefinitely* and keeping a log of technical problems found and solved, as well as all changes in protocol, computer software, or equipment. As noted earlier, ACOEM also recommends the purchase of spirometers with dedicated calibration check routines for use in the occupational setting.

Avoid Sensor Errors During Subject Tests

Even though a spirometer passes its check of calibration accuracy, subject test results can be invalidated by equipment errors occurring during subject tests in clinical practice.⁷ Two major types of errors are not infrequent during subject testing: contamination or blockage of a flow-type spirometer’s sensor and flawed setting of the zero-flow reference point. First, if a subject’s fingers, secretions, or water vapor block or contaminate a flow-type spirometer’s sensor, increasing its resistance, the test results will be falsely increased and become invalid. The impact of this problem is seen by comparing a valid test (Fig. 1) with a test having sensor contamination (Fig. 2). Such contaminated sensor problems are not identified as errors by currently available spirometers, and users need to visually recognize and delete these tests.

Second, most flow-type spirometers set a zero-flow reference point before each maneuver, or before each set of maneuvers. All flows during a subject’s subsequent expiration(s) are measured relative to this reference point. If a low level of airflow passes through the sensor in either direction while “zeroing” is in progress, the “zero” flow reference point will be incorrect. Such low-level airflow might be caused by slight sensor motion, or by background fans or forced air ventilation. Unless a zero-flow error is large, most spirometers do not alert the user to this problem.

If a low level of airflow moves through the sensor toward the subject during zeroing, in the direction opposite to the subject’s airflow during expiration, the spirometer will set a negative flow as “zero-flow.” This negative flow will not be reached during the subsequent expiration, and so the expiratory volume-time curves climb at a constant rate (never reaching “zero”) and the expiratory flow-volume curve draws a long limb to the right, showing increasing “volume” at a constant, very small flow rate. These patterns can be seen in both Fig. 3 and 4. The important difference between these two figures is that the zero-flow reference point is reset before each maneuver in Fig. 3, causing the error in the zero-flow reference points to vary among the curves. In contrast, in Fig. 4, the zero-flow reference point is set only once before a set of maneuvers, producing curves that are consistent, but erroneous, and making the error more difficult to recognize. Occluding the sensor during “zeroing” will prevent this problem.

In contrast, if a low level of airflow moves through the sensor away from the subject during zeroing, in the same direction as the subject’s air will move during expi-

ration, the spirometer will set a small positive flow as “zero-flow.” This positive flow will be reached during the subsequent expiration before the subject actually exhales to zero flow; the expiratory volume-time curve will plateau early and begin to descend as the subject’s slowing airflow becomes increasingly negative relative to the erroneous “zero-flow” point, drawing a pattern much like a leak in a volume spirometer as shown in Fig. 5. Occluding the sensor during “zeroing” will prevent this problem.

Zero-flow errors can also be caused by motion of a gravity-sensitive pressure-transducer during the subject test, disconnected or loose pressure tubing, a degrading sensor, or unstable electronics. If the zero-flow reference point is not set accurately, subsequent test results will be falsely increased or decreased and become invalid as shown in Figs. 3 to 5. It is important for the user to understand that no error message was generated for the tests shown in Figs. 3 to 5, and unless a zero-flow error is large, most spirometers do not identify this error.

Since these errors typically are not detected by spirometer software, health care professionals need to recognize the effects of contaminated sensors and zero-flow errors on test results and curve shapes. Both types of errors may produce very inconsistent results (failing to meet repeatability criteria, as discussed later), sometimes along with very large percent of predicted values, exceeding 130% to 140%. Such erroneous curves need to be deleted immediately (not saved), so that their results are not reported as the largest results from the test session. Figures 2 to 5 present examples of spirometers affected by these problems, and though not shown here, visual recognition of zero-flow errors may be improved if inspiratory as well as expiratory flow-volume curves are recorded.

The American College of Occupational and Environmental Medicine strongly recommends that users of flow-type spirometers become thoroughly familiar with the flawed patterns shown in Figures 2 to 5 and institute protocols of preventive actions as well as corrective actions if those patterns are observed. Such protocols might include occluding sensors during pre-maneuver sensor “zeroing,” frequent checks for sensor moisture and mucus deposits, maintaining sensors in an upright position to minimize accumulation of condensation, and keeping subjects’ fingers far from the sensor outlet.

CONDUCTING TESTS

Technician Training

In 1978, the OSHA Cotton Dust Standard stated that the goal of spirometry training courses is to provide technicians with the basic knowledge required to produce

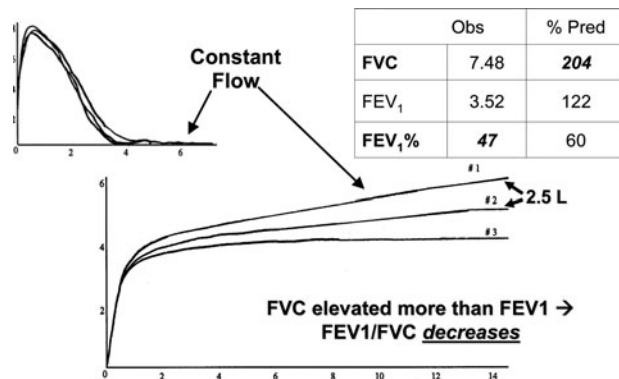


FIGURE 3. Zero-flow error No. 1—Flows are over-recorded and highly variable. This spirometer's zero-flow reference point was reset to a different level before each maneuver, causing the volume-time curves to be played apart. No error message was indicated by the spirometer. FVC is much more increased than FEV₁, falsely *reducing* the FEV₁/FVC. This problem usually produces erroneous "obstructive impairment" patterns. Occlude sensor whenever the sensor is being zeroed to avoid this problem. See the text for further details. Reprinted with permission from Townsend et al.⁷

meaningful test results. The OSHA noted that technicians need to be both motivated to do the very best test on every employee and also capable of judging the subject's degree of effort and cooperation.¹²

The National Institute for Occupational Safety and Health was designated as the agency responsible for reviewing and approving occupational spirometry training courses, based on the content specified by OSHA. In 2005, ATS/ERS endorsed NIOSH-approved courses as prototypes for technician training.³ Although most US companies are not involved in the cotton processing industry, successful completion of a NIOSH-approved spirometry course has been regarded as a benchmark and the

best practice in the occupational health setting for many years. The National Institute for Occupational Safety and Health Web page lists available courses in the United States.¹³ The National Institute for Occupational Safety and Health conducts on-site course audits and periodic reviews of course approval status, thereby monitoring the quality of its approved courses on an ongoing basis.

In 2009, NIOSH took additional steps to improve the technical quality of occupational spirometry testing, announcing that certificates of spirometry course completion now expire after 5 years, and initiating a program to review and approve spirometry refresher courses. The National Insti-

tute for Occupational Safety and Health-approved spirometry refresher courses focus on practical screening spirometry issues, and periodic refresher courses update knowledge, review testing problems, and help maintain technician enthusiasm during occupational spirometry testing.^{1,14,15} Technicians who successfully completed an initial NIOSH-approved spirometry course in 2000 or later can extend their course completion certificate by 5 additional years when they complete a NIOSH-approved spirometry refresher course, while those completing their initial course prior to 2000 are not eligible for this certificate extension. Those individuals must repeat the initial NIOSH-approved course. Available NIOSH-approved refreshers are also listed on the NIOSH Web page.¹³

The American College of Occupational and Environmental Medicine continues to strongly recommend that all technicians conducting occupational spirometry tests should successfully complete an initial NIOSH-approved spirometry course as well as a NIOSH-approved refresher course every 5 years.

Conducting the Test

The ATS/ERS continues to emphasize that technicians explain, *demonstrate*, and coach subjects throughout their maneuvers, even when workers have performed the test previously. Technicians need to emphasize maximal inhalations, hard initial blasts, and complete exhalations.

Occupational spirometry tests traditionally have been conducted with workers in the standing posture, permitting maximal inspirations and blasts on expiration, and yielding maximal forced expiratory volume

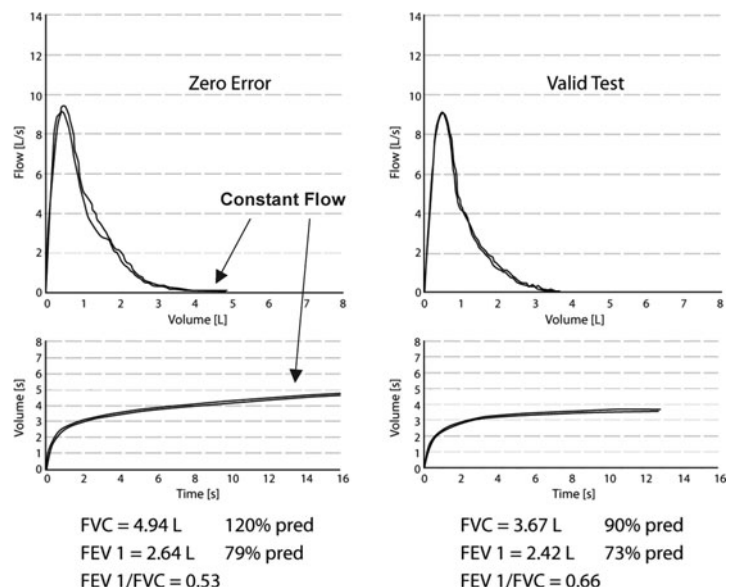


FIGURE 4. Zero-flow error No. 2—Flows are over-recorded but consistent. These tests were recorded by one subject: the valid test on the right has an accurate zero-flow reference point while the zero-error test on the left has an inaccurate zero-flow reference point. This spirometer's zero-flow reference is set only once, before the complete set of maneuvers, causing the curves on the left to be consistent but erroneous. No error message was indicated by the spirometer. FVC is much more increased than FEV₁, falsely *reducing* the FEV₁/FVC. This usually produces erroneous "obstructive impairment" patterns. Occlude the sensor whenever it is zeroed to avoid this problem. See the text for further details.

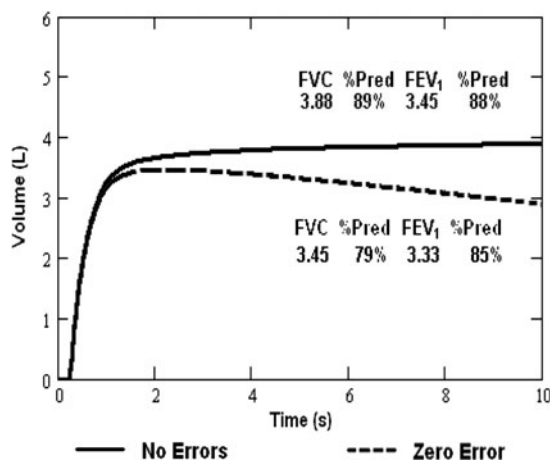


FIGURE 5. Zero-flow error No. 3—Flows are under-recorded. No error message was indicated by the spirometer. FVC is much more reduced than FEV₁, falsely *increasing* the FEV₁/FVC. This may produce erroneous “restrictive impairment” patterns and may mask true airways obstruction. Occlude sensor whenever the sensor is being zeroed to avoid this problem. See the text for further details.

in 1 second (FEV₁) and forced vital capacity (FVC).¹ The ATS/ERS particularly notes that subjects with “excessive weight at the midsection” achieve larger inspirations when standing.³ A chair without wheels is to be placed behind the subject, and the technician needs to be ready to assist the subject into the chair if they begin to feel faint. If there is a history of fainting or clinical illness, the test should be conducted in the sitting position. In all cases, the test posture needs to be documented and should be kept consistent over time whenever possible. Changes in test posture need to be taken into account when interpreting results over time.

The subject’s head is to be slightly elevated and he or she needs to sit or stand upright. The tongue cannot block the mouthpiece, and lips are to be tightly sealed around it. The ATS/ERS recommends that nose clips be used for all spirometry tests, which prevents extra breaths through the nose, a technical error that invalidates results but is not detected by most available spirometry software (see Fig. 12).

The American College of Occupational and Environmental Medicine continues to recommend that technicians need to explain, demonstrate, and actively coach workers to perform maximal inspirations, hard and fast expiratory blasts, and complete expirations. Testing should be conducted standing, unless workers have experienced problems with fainting in the past. Testing posture should be recorded on the spirometry record and the same posture needs to be used for serial tests over time. Disposable nose clips are recommended.

Testing Goal for a Valid Test

The ATS/ERS 2005 continues to define a valid spirometry test as having two

components: (1) at least three curves that are free of technical flaws (such curves are called “acceptable”) and (2) results for the FVC and FEV₁ that are consistent among the curves (such results are called “repeatable”), as defined later. Most healthy workers can achieve this testing goal, and up to eight maneuvers can be attempted.

Acceptable curves

The components of “acceptable” maneuvers—maximal inhalations, hard initial blasts, and complete exhalations—have not been changed. However, since some subjects experience difficulty in fully recording their FVCs, ATS/ERS now recognizes that curves that do not completely record the exhalation may be usable for FEV₁ measurement if they are free of hesitation and cough in the first second (shown in Figs. 6 and 7). The goal for an acceptable end of test is still to reach a 1-second FVC plateau and to try to exhale for 6 or more seconds of expiration.⁴ Figure 10 shows the impact of early termination of the maneuver for a worker with airways obstruction. However, it is recommended that subjects stop exhaling at any time if they cannot continue, and not perform multiple exhalations that are more than 15-second long, since such lengthy exhalations will not affect clinical decisions made about the subject.⁴ Spirometry users need to be aware that some workers, particularly young women and some men with small lung volumes, may reach their plateaus in less than 6 seconds—these tests are valid because they have reached the FVC plateau (Fig. 11), even if the spirometer is programmed to label all curves with exhalations less than 6 seconds as unacceptable. Examples of unacceptable curves caused by flawed testing technique, and a valid test

with an exhalation of less than 6 seconds in length are shown in Figs. 6 to 12.

Repeatable FVC and FEV₁

In 2005, ATS/ERS tightened the level of consistency to be achieved among test results: additional maneuvers should be attempted if the difference between the largest and second largest values of the FVC or FEV₁ exceeds 0.15 L (150 mL) among the acceptable curves. This difference between the largest and second largest values is now called “repeatability,” it was formerly termed “reproducibility,” and many spirometers label it “variability.” It is recommended that technicians strive to meet this goal during testing, attempting up to eight efforts, unless the subject is unable to continue with the test. Failure to achieve repeatability needs to be taken into account during the interpretation of results.

In the screening spirometry setting, lack of repeatability is often caused by a failure to inhale maximally to total lung capacity before each maneuver (Fig. 9). However, when FVC or FEV₁ repeatability is very poor, for example, more than 0.50 L (500 mL), sensor contamination or zero-flow errors are also likely (Figs. 2 and 3). In the absence of these technical problems, failure to achieve repeatability does not rule out interpretation of results, since it may also be caused by hyperresponsive airways or other respiratory disorders. The lack of repeatability needs to be documented and taken into account during the interpretation process.

The American College of Occupational and Environmental Medicine recommends that occupational spirometry tests strive to meet ATS/ERS criteria for a valid test, that is, recording three or more acceptable curves, with FVC and FEV₁ repeatability of 0.15 L (150 mL) or less. Failure to achieve repeatability in screening spirometry tests is often caused by inhalations that are not maximal. However, when flow-type spirometers are in use, very poor repeatability may indicate sensor contamination or zero-flow errors.

Reporting Results

The largest FVC and largest FEV₁ from all acceptable curves are reported as the test results even if they are drawn from different curves.⁴ The FEV₁/FVC is calculated using these two values. To permit a thorough review of a spirometry test, it is recommended that complete results from all acceptable curves also be shown on the spirometry report. As discussed later, ATS/ERS continues to strongly discourage evaluating the forced expiratory flow (FEF) rates, but if reported, all FEF, except for the peak expiratory flow, are to be drawn from one acceptable curve with the highest

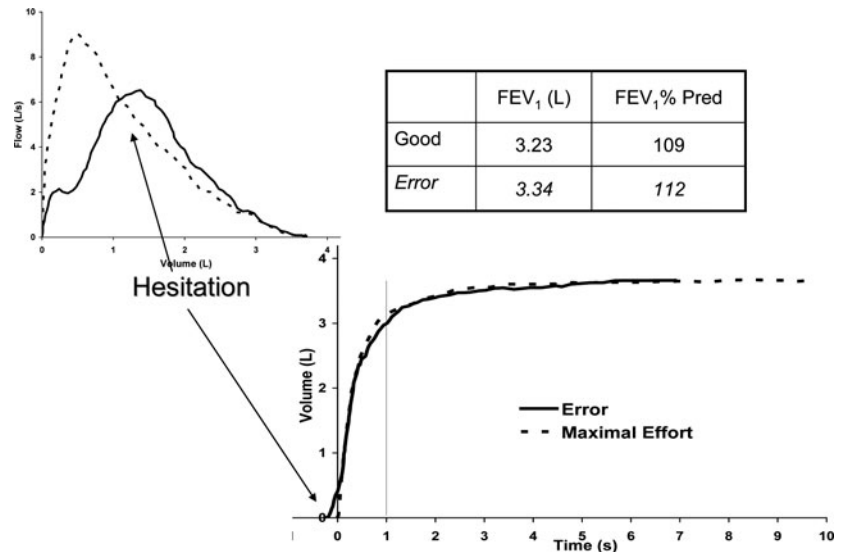


FIGURE 6. Excessive hesitation— invalid test, which must be deleted. Excessive hesitation moves the flow-volume peak to the right and draws a gradually climbing tail at the start of the volume-time curve. Large hesitations often increase the FEV₁ since the 1-second measurement point moves far to the right. Coach “blast out right away, as soon as you are ready” to solve this problem.

sum of (FEV₁ + FVC). The highest peak expiratory flow recorded from among all acceptable curves is to be reported.

The American College of Occupational and Environmental Medicine recommends that occupational spirometry test reports include values and curves from all acceptable curves and that the largest FVC and largest FEV₁ be interpreted, even if they come from different curves. Default spirometer configurations need to be examined and, if possible, adjusted to meet these recommendations.

Quality Assurance Reviews

In addition to emphasizing technician training, recent ATS/ERS and ATS spirometry

standardization statements strongly recommend that spirometry be reviewed periodically to provide regular feedback on the quality of each technician’s testing.^{3,14} Quality assurance reviews can be performed on electronically saved tracings or on copies of spirometry. It is recommended that samples of randomly selected tests, all invalid tests, and tests with abnormally low or improbably high results (FEV₁ or FVC > 130% of predicted) be reviewed. Because of their profound impact on test results, figures illustrating some of the technical errors that can affect spirometry test results are presented in the 1994 ATS spirometry update¹⁶ and included in Figs. 2 to 12 in this statement.

The American College of Occupational and Environmental Medicine highly recommends that facilities performing occupational spirometry tests establish ongoing programs that provide quality assurance review of spirometry on a regular basis. The frequency of such reviews needs to be at least quarterly, and more often if technicians are inexperienced or if poor technical quality is observed. As recommended by the California Department of Public Health, the goal of such reviews is to maintain the technical quality of spirometry tests at a high level, assuring that 80% or more of an occupational health program’s spirometry tests are technically acceptable. It is recommended that reviews be conducted by those experienced in recognizing and correcting flawed spirometry tests results.¹¹

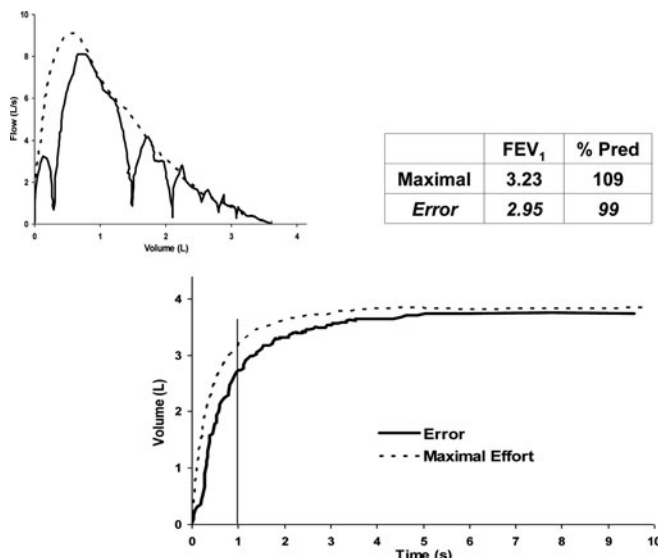


FIGURE 7. Cough in first second—Invalid test, which must be deleted. Cough in the first second produces steep interruptions in the flow-volume curve and subtle steps in the first second of the volume-time curve. Coughs often reduce the FEV₁. Try offering a drink of water to solve this problem.

COMPARING RESULTS WITH REFERENCE VALUES

After establishing the technical validity of a test, spirometry results are usually evaluated at each measurement date as well as longitudinally, comparing a worker’s current results with previous test results. Most available spirometer software performs a traditional (“cross-sectional”) evaluation at the time of the test, comparing the worker’s results with the reference range expected for his/her current demographic characteristics. Recommendations for this approach are summarized in this section. Fewer spirometers evaluate change over time or “trending,” and criteria for longitudinal abnormality are less well established. Recommendations for longitudinal interpretation are summarized in the following section.

Three critical aspects of traditional pulmonary function evaluation influence the interpretation: (1) the source of the reference values used; (2) how the

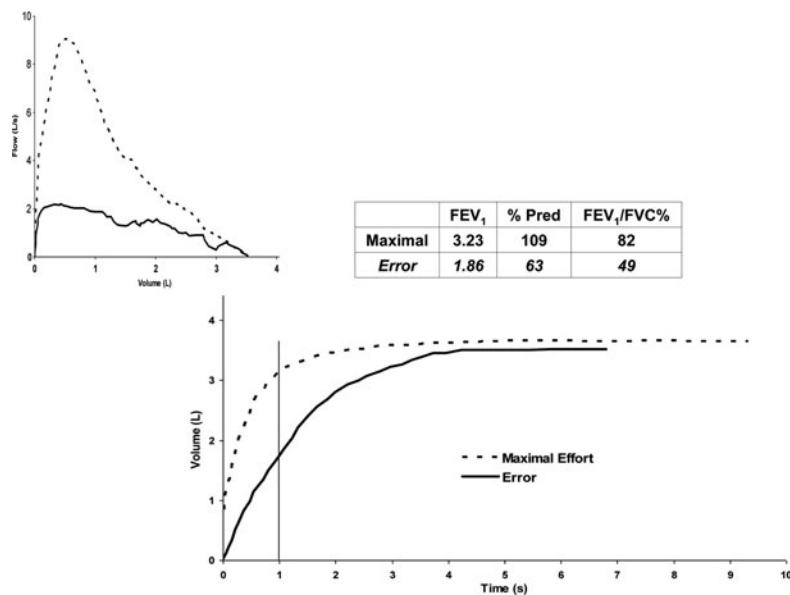


FIGURE 8. No blast—reduced FEV₁. No blast produces a flow-volume curve with no sharp peak—the weaker the push, the less peaked the flow-volume curve. A weak push (or no blast at all, as shown here) reduces the FEV₁ significantly and may be caused by a subject trying to “save” their air so that they can exhale for many seconds. This error will cause erroneous “obstructive impairment” patterns. Coach “blast out hard and fast, and keep that initial push going” to solve this problem.

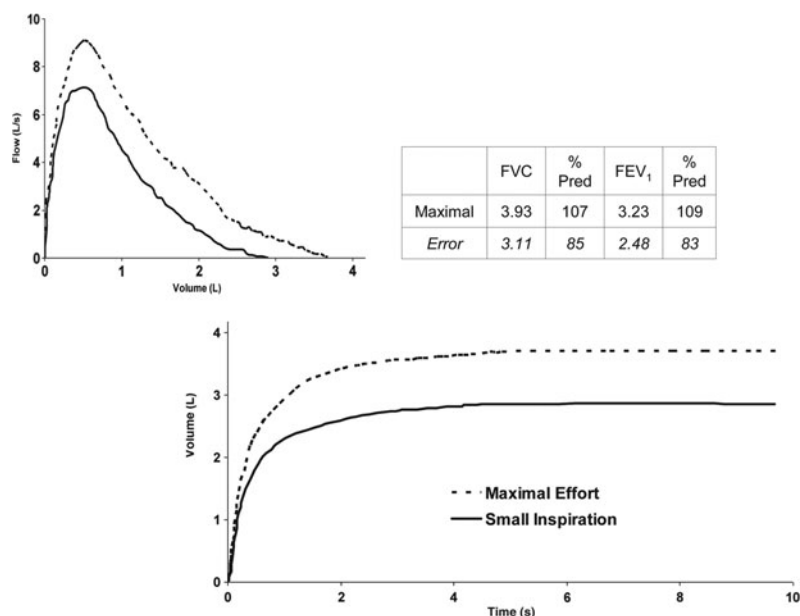


FIGURE 9. Submaximal inspiration—reduced FEV₁ and FVC. Failure to maximally inhale to total lung capacity may be the most common screening spirometry error. It often occurs when technicians feel the need to rush the inhalation so that the spirometer will record the subject’s expiration before “timing out.” Since it is difficult for untrained subjects to achieve repeatability when inspirations are not maximal, the test may be flagged as invalid due to lack of repeatability. This error may cause erroneous “restrictive impairment” patterns. Coach “fill your lungs” to solve this problem.

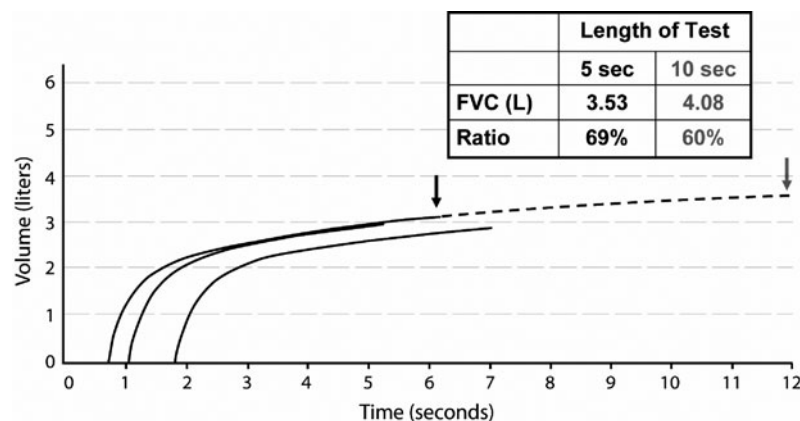


FIGURE 10. Early termination at 5 seconds (solid lines)—reduced FVC and increased FEV₁/FVC. The dashed line shows how much the “FVC” would have increased with only 5 more seconds of expiration. This error may cause true airways obstruction to go undetected. Coach the patient to “Keep exhaling until I tell you to stop” to solve this problem.

25 yr 62" WF	Observed	% Pred
FVC	3.76 L	107 %
FEV1	3.30	112 %
FEV1/FVC	88%	105%
Time (FET)	4.5 sec	--

FIGURE 11. Valid test—FVC plateau achieved in less than 6 seconds. Subject has recorded a 1 second FVC plateau, so the test is valid, though most spirometers will display an error message because the exhalation is less than 6 seconds. Ignore the error message in this case, since reaching the FVC plateau is the first criterion for a valid end-of-test.

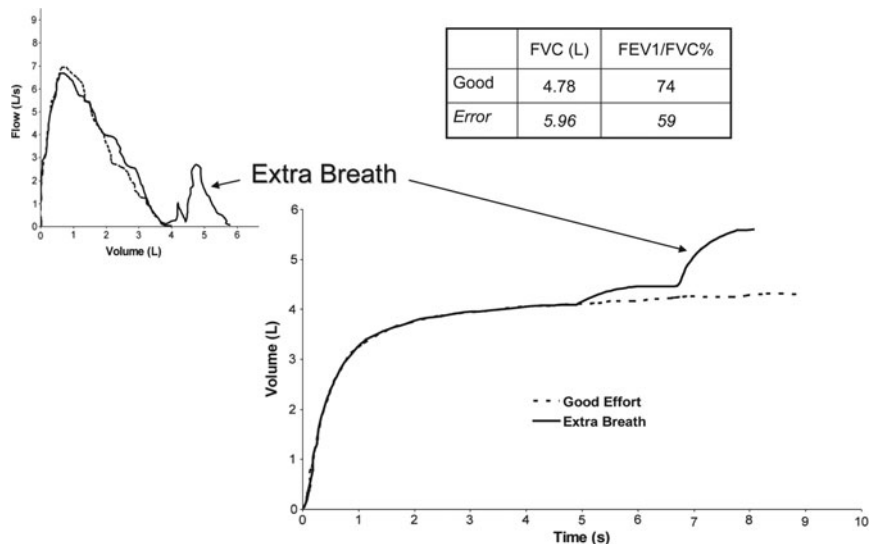
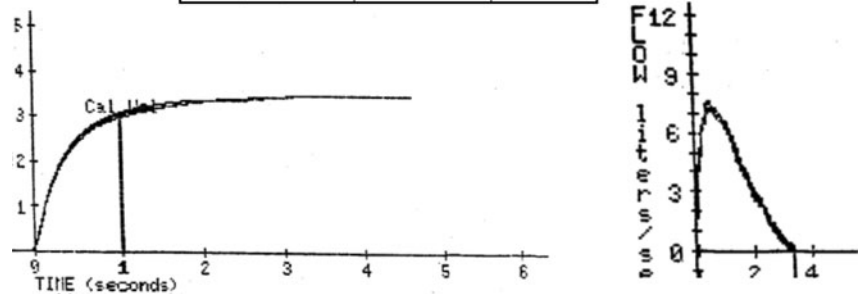


FIGURE 12. Extra breaths through the nose—invalid test. The flow-volume curve shows multiple maneuvers and the volume-time curve shows increasing steps at the end of the test. Delete the test since the FVC is erroneously elevated and will be reported as the highest value for the FVC. The resulting falsely reduced FEV₁/FVC will produce an erroneous “obstructive impairment” pattern. This error is not identified by most spirometers, so health care professionals need to visually recognize and delete it. The best solution is to have the subject wear nose clips.

reference values are adjusted when a worker’s race/ethnicity differs from the reference study subjects’; and (3) selection of the interpretation algorithm used to categorize pulmonary function as normal or abnormal, that is, the choice of lung function parameters to be evaluated and the sequence in which they are examined.

The American College of Occupational and Environmental Medicine’s 2000 spirometry statement identified normal, obstructive, and restrictive impairment patterns, as well as grading the severity of those impairments. However, since 2005, several conflicting schemes are now recommended for grading severity.^{5,17,18} Since the most critical concern of occupational screening spirometry is to separate abnormal from normal, this ACOEM statement focuses only on that task, for which there is strong consensus. Choice of a severity-grading scheme will be left to the practitioner’s discretion, depending upon the cir-

cumstances in which they are conducting spirometry tests.

Reference Values

Reference values define the expected average and lower boundary of the reference range for individuals with the same demographic characteristics as the worker being tested. Reference values are generated from research studies of asymptomatic never smokers of varying ages and heights, both genders, and sometimes varying ethnic/racial backgrounds. Subject ethnic/racial group is based on self-report, and height in stocking feet needs to be measured periodically. The relationships of pulmonary function parameters with these four demographic variables are summarized in regression equations, which produce average “predicted” values and fifth percentile lower limits of normal (LLN). Since predicted values and LLNs describe the average and the bottom of the reference range

based on a single research study, both indices need to be drawn from a single source of reference values.^{5,19}

Many reference value studies have been conducted in a single geographical location,^{20,21} but ATS/ERS,⁵ ACOEM,¹ and the sixth edition of the *American Medical Association (AMA) Guides to the Evaluation of Permanent Impairment*¹⁸ recommend using reference values generated from the 3rd National Health and Nutrition Examination Survey (NHANES III).²² The 3rd National Health and Nutrition Examination Survey studied a random sample of never smokers from across the United States, using spirometry testing of high technical quality, and including three ethnic/racial groups. Therefore, race-specific NHANES III reference equations are available for whites, African Americans, and Mexican-Americans. If the NHANES III reference values are not available on older spirometers, the Crapo reference values²⁰ are closer

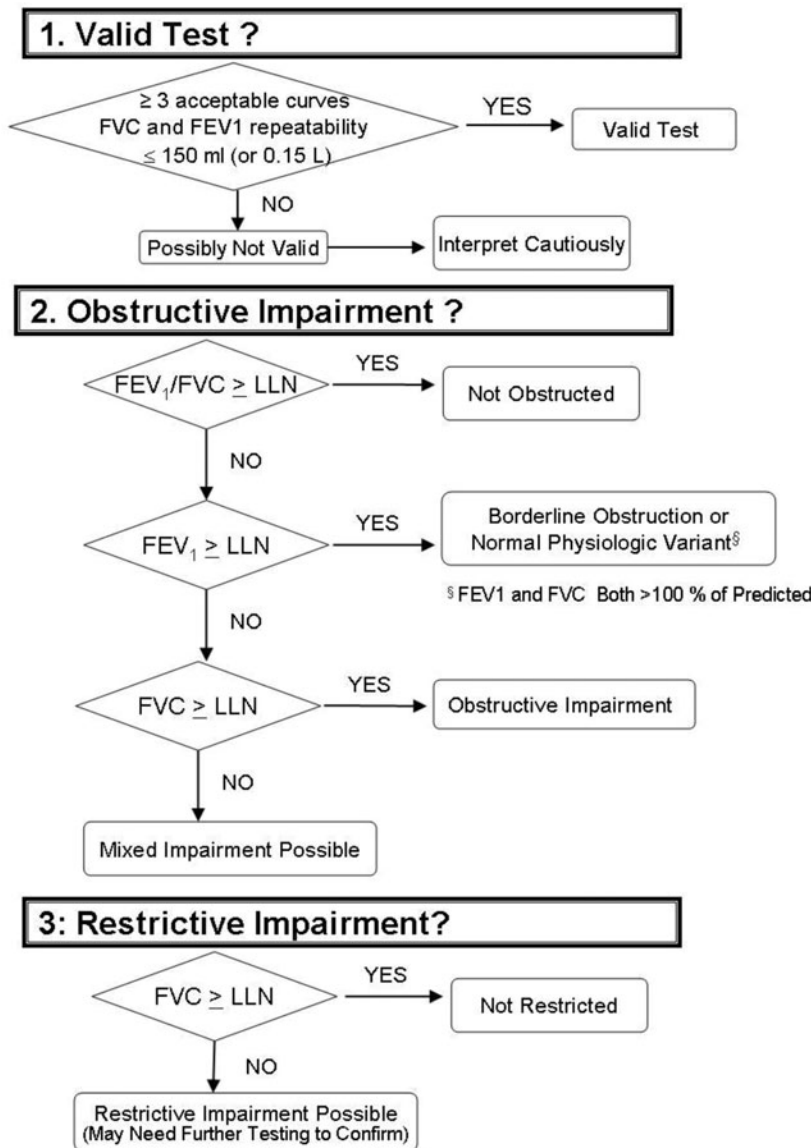


FIGURE 13. 2011 Spirometry interpretation algorithm. LLN indicates lower limit of normal.

to the NHANES⁷ values than other available prediction equations.²³

The American College of Occupational and Environmental Medicine, along with ATS/ERS and the AMA guides sixth edition, endorses use of the NHANES III (Hankinson) reference values in the occupational setting, unless a regulation mandates another specific set of reference values. National Health and Nutrition Examination Survey reference values can be calculated for individuals, using a reference value calculator at www.cdc.gov/niosh/topics/spirometry/RefCalculator.html. Tables of NHANES III predicted values, but not LLNs, can be obtained at www.cdc.gov/niosh/topics/spirometry/nhanes.html. If NHANES III reference values are not available on a spirometer, ACOEM now recommends selecting the Crapo prediction equations, and only using the Knudson 1983

equations if the Crapo equations are not available. Since reference values vary significantly and may strongly affect the percent of predicted values, the selected reference values need to be documented on the spirometry printout.

Race Adjustment of Predicted Values and Lower Limits of Normals

If a worker's self-reported race/ethnicity is the same as that of the reference value group, no adjustment of the worker's reference values is required. Since NHANES III reference values were generated specifically for whites, African Americans, and Hispanics, the predicted values and LLNs are not adjusted when workers of these race/ethnicity groups are tested. However, when Asian workers (ie, Chinese, Japanese, East Indian, or Pak-

istani) are tested, race-specific NHANES reference values are not available. Though less desirable than race-specific values,²⁴ white-predicted values and LLNs for FVC and FEV₁ need to be multiplied by a scaling factor to account for the larger thoracic cages observed in whites when compared with Asians of the same age, height, and gender. The scaling factor recommended by ATS/ERS in 2005, 0.94, was based on two small studies⁵ and there is recent evidence that this factor may not be optimal. Studies reported since 2005 indicate that the previously used scaling factor of 0.88 may still be the most appropriate choice for Asians as well as for African Americans.^{25,26}

If NHANES III reference values are not available to evaluate an African American's pulmonary function, and the only available reference values are drawn from studies of whites, for example, Crapo²⁰

or Knudson²¹ predicted values, the white predicted values and LLNs for FVC and FEV₁ need to be multiplied by 0.88 to obtain appropriate predicted values and LLNs for the African American employee.^{1,5} The single exception to this recommendation is for cotton-exposed workers for whom the Knudson 1976²⁷ prediction equations and a scaling factor of 0.85 must be used for African American workers, as mandated by OSHA.¹²

The American College of Occupational and Environmental Medicine and ATS/ERS recommend that race-specific NHANES III reference values be used whenever possible, basing the worker's race/ethnicity on self-report. To evaluate Asian workers, ACOEM continues to recommend that white predicted values and LLNs for FVC and FEV₁ be multiplied by a scaling factor of 0.88 to obtain appropriate Asian reference values. If NHANES III reference values are not available when African American workers are tested, and white-predicted values need to be used, ACOEM recommends applying a scaling factor of 0.88 to the white-predicted values and LLNs for FVC and FEV₁, unless other practices are mandated by an applicable regulation. *Note that FEV₁/FVC predicted values and LLNs are not race-adjusted.*

Interpretation Algorithm

For two decades, ATS has consistently recommended applying a stepwise algorithm to three pulmonary function parameters to interpret spirometry results.^{5,19} The American College of Occupational and Environmental Medicine endorsed this approach in its 2000 statement.¹ Since consensus exists on how to distinguish normal from abnormal results, and which measurements identify obstructive or restrictive impairment, these determinations are presented in Fig. 13.

In contrast to the determination of normal/abnormal, recommendations for grading severity of impairment are now quite disparate,^{5,17,18} and so this statement's interpretation algorithm shown in Fig. 13 does not grade severity of impairment. As noted later, practitioners need to choose an impairment-grading scheme that is most appropriate for their specific needs.

Lower Limit of Normal Defines Abnormality

Since 1991, the ATS has officially endorsed using the fifth percentile, the point below which 5% of nonexposed asymptomatic subjects are expected to fall, as the lower limit of the reference range (LLN).¹⁹ Though two older cutoff points for abnormality have re-emerged in some chronic obstructive pulmonary disease screening recommendations, that is, 80% of the pre-

dicted value, and an observed FEV₁/FVC ratio less than 0.70,²⁸ the ATS/ERS official recommendations continue to explicitly discourage use of these definitions.^{5,19} As pulmonary function declines with age, the fifth percentile LLN also declines, labeling only 5% of normal individuals in each age group as "abnormal." In contrast, as age increases, increasing proportions of nonexposed healthy individuals fall below 80% of predicted or a measured FEV₁/FVC ratio of 0.70, creating an increasing pool of false positives in an aging workforce.^{19,29,30} These fixed definitions of abnormality also yield some false negatives in young workers. As recommended by the ATS since 1991,^{5,19} using the fifth percentile LLN to define abnormality for the major spirometry measurements avoids these problems. As described later, the LLN is used to identify both obstructive and restrictive impairment patterns.

Obstructive Impairment

As shown in Fig. 13, the first step in interpreting spirometry test results is to determine whether a valid test has been performed or if more maneuvers may be needed. Once test validity has been established, Step 2 shows that the FEV₁/FVC is the first measurement to be evaluated, to "distinguish obstructive from nonobstructive patterns."¹⁹ When the FEV₁/FVC and FEV₁ are both less than their LLNs, airways obstruction is present. However, when FEV₁/FVC is less than LLN, but FEV₁ is more than its LLN, borderline obstruction or a normal physiologic variant may exist. The ATS/ERS cautions that an FEV₁/FVC below the LLN combined with FVC and FEV₁ more than 100% of predicted is "sometimes seen in healthy subjects, including athletes" and may be due to dysanaptic growth of the alveoli. This pattern is labeled as a possible "normal physiologic variant,"^{5,19} and is not unusual among physically fit nonsmoking emergency responders, firefighters, and police. However, if these healthy workers are exposed to known hazardous substances, the possibility of obstructive impairment needs to be considered when a reduced FEV₁/FVC is observed.

Though not included in Fig. 13, all grading schemes for severity of airways obstruction rely on the FEV₁ percent of predicted, applying one of several definitions, whose "number of categories and exact cut-off points are arbitrary."^{5,17,18} Widely used schemes are based on the 1986 ATS respiratory impairment categories, which define an FEV₁ down to 60% of predicted as mild obstruction, an FEV₁ between 41% and 59% of predicted as moderate obstruction, and an FEV₁ of 40% or less of predicted as severe obstruction, as was done in the 2000 ACOEM statement.^{1,17} These

cut points from the 1986 ATS statement are consistent with those used in OSHA's cotton dust standard¹² and they largely overlap those employed in the sixth edition of the AMA guides.¹⁸ However, these cut points are lower than the sample method presented by the ATS/ERS in 2005.⁵

Restrictive Impairment

In the absence of airways obstruction (FEV₁/FVC \geq LLN), Step 3 of Fig. 13 evaluates the FVC, to determine whether restrictive impairment may exist. If FVC is less than LLN, restrictive impairment is possible, and it may need to be confirmed using additional tests of pulmonary function, such as lung volume measurements. In the presence of airways obstruction (FEV₁/FVC < LLN), FVC less than LLN indicates a possible mixed impairment pattern, and its restrictive component may also need to be confirmed by additional PFTs.

In 2005, ATS/ERS recommended grading restrictive impairment, as well as airways obstruction, using the FEV₁% of predicted.⁵ From a practical standpoint, this may be reasonable since both the FVC and FEV₁ are reduced as restrictive impairment progresses, and the common technical problems of early termination of maneuvers and zero-flow errors are less likely to impair the accuracy of the FEV₁ than the FVC. However, for workers with mixed impairment patterns, grading the restrictive impairment using FEV₁% of predicted might slightly overstate the severity of restriction due to the coexisting obstructive reduction of the FEV₁.

By relying on the FEV₁% of predicted, the ATS/ERS 2005 definitions of restrictive impairment severity now differ significantly from those presented in the AMA guides sixth edition.¹⁸ The AMA guides remains closer to the ATS 1986 respiratory impairment definitions, labeling mild restriction as FVC between 60% and 69% of predicted, moderate restriction as FVC between 51% and 59% of predicted, and severe restriction as an FVC between 45% and 50% of predicted.

Forced Expiratory Flow Rates

Because of the wide variability of the FEF_{25%-75%} and the instantaneous flow rates, both within and between healthy subjects, ATS/ERS continues to strongly discourage their use for diagnosing small airway disease in individual patients^{5,19} or for assessing respiratory impairment. Interpretation of FEF_{25%-75%} and other flow rates is not recommended if the FEV₁ and the FEV₁/FVC are within the reference range, although the flow rates may be used to confirm the presence of airways obstruction in the presence of a borderline FEV₁/FVC.^{5,19}

The American College of Occupational and Environmental Medicine continues to strongly recommend that occupational medicine practitioners follow the ATS/ERS algorithm for separating normal from abnormal test results. Presence of airways obstruction is indicated by an FEV₁/FVC below the worker's LLN, and presence of possible restrictive impairment is indicated by an FVC less than LLN. Practitioners need to remember that an FEV₁/FVC that is barely abnormal, in the presence of both FEV₁ and FVC more than 100% of predicted, may indicate a normal physiologic variant pattern in healthy non-smoking populations, such as emergency responders. However, if such healthy workers are exposed to known respiratory hazards, it is recommended that the possibility of airways obstruction be also considered when an abnormal FEV₁/FVC is observed.

LONGITUDINAL INTERPRETATION

The goal of evaluating change over time in medical surveillance programs is to identify pulmonary function that may be declining faster than expected over time. Confirmation of an excessive decline then needs to trigger referral for further medical evaluation to determine whether possible injury or harm has been caused by workplace or other exposures. Finding excessive declines also needs to prompt interventions such as removal from hazardous exposures, smoking cessation, initiation of appropriate respiratory protection, or identification of new hazardous exposures. Large short-term declines have served as important early indicators of respiratory disease in some food flavorings manufacturing workers.³¹⁻³⁶ In contrast, small short-term lung function declines are variable,³⁷⁻⁴⁰ though long-term excessive loss of pulmonary function may predict increased respiratory disease and mortality.^{41,42}

Longitudinal evaluation is particularly important for many healthy workers whose baseline pulmonary function is above average (>100% predicted). Since such workers start off so far above average, they can experience significant lung function decline without falling below the cross-sectional LLN and being labeled "abnormal" on any single PFT. If high-quality serial spirometry tests are recorded over an adequate length of time, longitudinal evaluation may reveal deterioration earlier than repeated traditional cross-sectional evaluations.^{2,9,43} Factors other than workplace exposures that influence lung function change over time include technical aspects of test performance, weight gain,⁴⁴⁻⁴⁶ other lung conditions (eg, asthma), and personal habits (eg, smoking). The American College of Occupational and Environmen-

tal Medicine has discussed some of these issues in detail.²

The importance of conducting valid tests, maintaining high technical quality, and using spirometers that exceed minimum standards for accuracy and precision cannot be overstated when evaluating change over time.^{2,11} As discussed earlier, both over- and under-recording of results can be caused by errors in technique, flawed spirometer calibration, or sensor problems that occur during the subject test. Such problems can bias the estimates of change, for example, making declines appear "excessive" if a baseline is falsely elevated, or conversely, masking a true loss if the baseline is under-recorded or follow-up results are over-recorded.

Of particular concern in the occupational setting is the variation in technical quality and testing protocols that occurs when occupational health vendors, spirometers, or both are changed frequently. Such inconsistency makes it difficult to accurately measure a worker's change in pulmonary function over time. On-going quality assurance (QA) reviews of spirometry test results are critical in such situations. As an adjunct to a QA program, public domain software, Spirola (Centers for Disease Control and Prevention/NIOSH, Atlanta, GA),⁴⁷ is available to help users examine the variability of their serial pulmonary function data, which is often increased by poor technical quality. However, users need to remember that some respiratory diseases also cause increased variability over time, and that technical errors, which are consistent over time may bias spirometry results without increasing their variability.

Occupational medicine practitioners need to determine whether monitoring decline in pulmonary function has been shown to be effective in screening for a particular outcome disease of interest. There is general consensus that early detection of accelerated pulmonary function decline in flavoring and microwave-popcorn manufacturing workers should trigger comprehensive medical evaluation and workplace interventions.¹¹ However, the effectiveness of monitoring longitudinal pulmonary function is less clearly demonstrated in other occupational settings. Therefore, practitioners need to regard the finding of a possible excessive decline as an opportunity to further assess an individual's health, and not use it as a label or to stigmatize a worker. Such inappropriate labeling may negatively impact the worker's employment status while not gaining him/her any improvement in respiratory health.

Longitudinal interpretation

Clinicians have accumulated many decades of experience in the traditional eval-

uation of patient spirometry test results relative to the cross-sectional reference range. In contrast, relatively little evaluation of lung function loss over time has occurred. Since 1991, ATS has recommended that a year-to-year change in healthy individuals needs to exceed 15% before it is considered as clinically meaningful, so that "changes" in lung function are not likely to be caused only by measurement variability.^{5,19} In 1995, NIOSH adopted this definition⁴⁸ and recommended that an age-adjusted percent decline from baseline be calculated, with medical referral if the FEV₁ declined by 15% or more after taking aging effects into account.

To provide some guidance for occupational medicine practitioners, ACOEM adopted these definitions and approaches when it defined its longitudinal normal limit in 2004.² A worker's longitudinal normal limit is derived specifically from his/her baseline results, and corresponds to a 15% drop from the baseline, after allowing for expected average loss due to aging. Falling below the longitudinal normal limit means that the worker has lost more lung function than was expected due to aging and measurement variability. After a low value is confirmed, medical referral is recommended. In 2007, the California Department of Public Health recommended using the cutoff of a 15% decline to trigger a medical evaluation for flavor manufacturing workers.¹¹ This cutoff was chosen to avoid the false positives that are likely to occur when pulmonary function is measured in many non-standardized, real-world clinic situations.

And finally, NIOSH researchers have been working to expand the practice of longitudinal evaluation of pulmonary function, developing public domain software, Spirola, for this purpose, and analyzing several large standardized databases, to determine how tightly the longitudinal lower limit of normal might be set when high quality test results are evaluated over time.^{8,47} The National Institute for Occupational Safety and Health estimates of abnormal longitudinal change, obtained from good quality results for normal healthy workers, are generally smaller than the 15% recommended by ACOEM, ATS/ERS, and the 1995 NIOSH criteria document, and so a range of cutoffs for excessive pulmonary function declines may emerge as clinical experience with these measurements accumulates. For now, the recommendation of a NIOSH Health Hazard Evaluation may be generally appropriate for longitudinal evaluations of pulmonary function: "... workers with FEV₁ falls of about 10% to 15% (*depending on spirometry quality*) [emphasis added] from baseline should be medically evaluated."⁴⁹

The American College of Occupational and Environmental Medicine strongly

recommends that the interpretation of pulmonary function change over time requires both an evaluation of the technical quality of the tests and an adequate length of follow-up. When high-quality spirometry testing is in place, ACOEM continues to recommend medical referral for workers whose FEV₁ losses exceed 15%, after allowing for the expected loss due to aging. Smaller declines of 10% to 15%, after allowing for the expected loss due to aging, may be important when the relationship between longitudinal results and the endpoint disease is clear. These smaller declines must first be confirmed, and then, if the technical quality of the pulmonary function measurement is adequate, acted upon.

Pre- to Postbronchodilator Changes in Pulmonary Function

There is general agreement that a pre- to postbronchodilator increase in FEV₁ (and/or FVC) needs to be at least 12% of the initial value and 0.2 L to be called significant, that is, a bronchodilator response that is suggestive of airways hyperreactivity.^{5,50-52} Percent change from the initial value is calculated as [(initial value – postbronchodilator value)/initial value] × 100. However, failure to achieve such a response to bronchodilators does not completely exclude the possibility of reversible airways disease, and testing may have to be repeated more than once. Attention focuses first on changes in the FEV₁ and then, secondly, on the FVC because changes in the FVC may be produced by varying lengths of expiration recorded before or after the bronchodilator.

The American College of Occupational and Environmental Medicine continues to recommend that a pre- to postbronchodilator increase in FEV₁ (and/or FVC) be 12% or more of the initial value and at least 0.2 L to be considered suggestive of reversible obstructive airways disease. The American College of Occupational and Environmental Medicine also concurs with the ATS and the AMA that determinations of permanent impairment need to use a worker's best values for FVC and FEV₁, whether recorded before or after bronchodilator administration.

ACOEM RECOMMENDATIONS—2011

1. Equipment Performance

The American College of Occupational and Environmental Medicine recommends that facilities performing occupational spirometry tests maintain a procedure manual documenting equipment type, spirometer configuration, manufacturer's guidelines, calibration log, service and repair records, personnel training, and

standard operating procedures. Such a manual will permit troubleshooting if problems arise with test results.

a. Spirometer specifications

1. The American College of Occupational and Environmental Medicine recommends that spirometers of all types meet or exceed recommendations made by ATS/ERS 2005 and, eventually, by ISO 26782:

- Performance-based criteria for spirometer operation, including, for example, accuracy, precision, linearity, frequency response, expiratory flow impedance, and other factors;
- Minimum sizes and aspect ratios for real-time displays of flow-volume and volume-time curves and graphs in hard-copy printouts (see the Appendix); and
- Standard electronic spirometer output of results and curves.

2. It is also recommended that spirometers which will be used in the occupational setting:

- Store all information from up to eight maneuvers in a subject test session;
- Permit later editing and deletion of earlier flawed test results;
- Be capable of including all flow-volume and volume-time curves and all test results from at least the three best maneuvers, and preferably from all saved efforts, in the spirometry test report;
- Provide computer-derived technical quality indicators;
- Provide a dedicated routine for verifying spirometer calibration; and
- Save indefinitely a comprehensive electronic record of all calibration and calibration verification results.

b. Validation testing of spirometers

If spirometers are purchased for use in the occupational health setting, ACOEM strongly recommends that:

- The manufacturer needs to provide written verification that the spirometer successfully passed its validation testing, preferably conducted by an independent testing laboratory, and that the tested spirometer and software version correspond with the model and software version being purchased; and
- The spirometer needs to meet the ATS/ERS recommended minimum real-time display and hardcopy graph sizes for flow-volume and volume-time curves and ISO minimum aspect ratios for these displays, as well as providing a standard spirometer electronic output (see the Appendix).

c. Spirometer accuracy checks

The American College of Occupational and Environmental Medicine recommends that:

- Spirometer accuracy be checked daily when in use, following the steps outlined in this document;
- Tracings and records from these checks be saved indefinitely;
- A log is kept of technical problems found and solved, as well as all changes in protocol, computer software, or equipment; and
- Spirometers purchased for use in the occupational setting have dedicated calibration check routines (as noted earlier).

d. Avoiding sensor errors during subject tests

- Users of flow-type spirometers need to recognize the flawed curves and test results that may be caused by sensor contamination or zero-flow errors (Figs. 2 to 5); and
- Protocols need to be established and used to prevent these errors from occurring and to correct the errors if they do occur. See the text for specific suggestions.

2. Conducting Tests

a. Technician training

All technicians conducting occupational spirometry tests should successfully complete a NIOSH-approved spirometry course initially, and a NIOSH-approved refresher course every 5 years.

b. Conducting the test

- Technicians need to explain, demonstrate, and actively coach workers to perform maximal inspirations, hard and fast expiratory blasts, and complete expirations.
- Testing should be conducted standing, positioning a sturdy chair without wheels behind the subject, unless the subject has previously experienced a problem with fainting.
- Record test posture on the spirometry record and use the same posture for all serial tests over time.
- Disposable nose clips are recommended.

c. Testing goal for a valid test

- To achieve a valid test, occupational spirometry should attempt to record 3 or more acceptable curves, with FVC and FEV₁ repeatability of 0.15 L (150 mL) or less. A poster portraying many unacceptable curves has recently been published by NIOSH.⁵³ See the text for definitions of terms.
- Failure to achieve repeatability is often caused by submaximal inhalations, though very poor repeatability (eg,

> 0.50 L) may indicate sensor contamination or zero-flow errors.

- Failure to achieve repeatability needs to be taken into account during the interpretation of results.

d. Reporting results

- Spirometry test reports need to present results and curves from all acceptable maneuvers to permit technical quality to be fully evaluated.
- The largest FVC and largest FEV₁ are interpreted, even if they come from different curves. Note that many currently available spirometers fail to meet this ATS/ERS and OSHA requirement.
- Test reports need to list the source of the reference values used as well as displaying the LLNs for clinician evaluation.
- Default spirometer configurations need to be examined and often adjusted, if possible, to meet these requirements and recommendations.

e. Quality assurance reviews

- The American College of Occupational and Environmental Medicine recommends that facilities performing occupational spirometry tests need to establish on-going programs providing QA reviews of spirometry tests.
- Reviews need to be conducted at least quarterly, and more often if technicians are inexperienced or if poor technical quality is observed.
- The goal of such reviews is to assure that 80% or more of an occupational health program's spirometry tests are technically acceptable.
- It is recommended that QA reviewers be experienced in recognizing and correcting flawed spirometry test results.

3. Comparing Results With Reference Values

a. Reference values

- The American College of Occupational and Environmental Medicine recommends that the NHANES III (Hankinson) reference values be used unless a regulation mandates another specific set of reference values.
- If NHANES III reference values are not available on older spirometers, ACOEM recommends using the Crapo prediction equations, and only using the Knudson 1983 equations if neither NHANES nor Crapo equations are available.

b. Race-adjustment of predicted values and lower limits of normal

- Use NHANES III race-specific reference values, basing a worker's race/ethnicity on self-report.

- Apply a scaling ("race-adjustment") factor of 0.88 to white-predicted values and LLNs for FVC and FEV₁ to obtain appropriate reference values for Asian workers.
- If NHANES III reference values are not available when testing African American workers, apply a scaling factor of 0.88 to white-predicted values and LLNs for FVC and FEV₁, unless other practices are mandated by an applicable regulation.
- The predicted FEV₁/FVC and its LLN are not race adjusted.

c. Interpretation algorithm

- To separate normal from abnormal test results, first examine the FEV₁/FVC to determine whether obstructive impairment is present, and then evaluate the FVC to determine whether restrictive impairment may exist. The FEV₁ is examined if the FEV₁/FVC indicates possible obstructive impairment, as shown in Fig. 13.
- All three indices of pulmonary function are considered abnormal if they fall below their fifth percentile LLN. Fixed cut-off points for abnormality such as 80% of the predicted value or an observed FEV₁/FVC ratio less than 0.70 should not be used in the occupational health setting.
- An FEV₁/FVC that is barely abnormal, in the presence of FEV₁ and FVC more than 100% of predicted, may indicate a normal physiologic variant pattern in healthy nonsmokers. However, if such healthy workers are exposed to known respiratory hazards, clinical judgment is needed to evaluate the possibility of early airways obstruction.

4. Evaluating Results Over Time

a. Longitudinal interpretation

- Evaluate technical quality of the spirometry tests and the adequacy of the follow-up period before interpreting change in pulmonary function over time.
- The American College of Occupational and Environmental Medicine recommends that FEV₁ losses exceeding 15% since baseline, after allowing for the expected loss due to aging, trigger further medical evaluation when spirometry is of high technical quality.
- The American College of Occupational and Environmental Medicine recommends that a confirmed FEV₁ decline of 10% to 15% since baseline, after allowing for the expected loss due to aging, would trigger further medical evaluation, when loss of FEV₁ is known to be related to an endpoint disease and test quality is adequate.

b. Pre- to postbronchodilator changes in pulmonary function

- A pre- to postbronchodilator FEV₁ or FVC increase of 12% of the initial value and 0.2 L is suggestive of reversible obstructive airways disease.
- Determinations of permanent impairment need to be based on a worker's best values for FVC and FEV₁, whether recorded before or after a bronchodilator.

ACKNOWLEDGMENTS

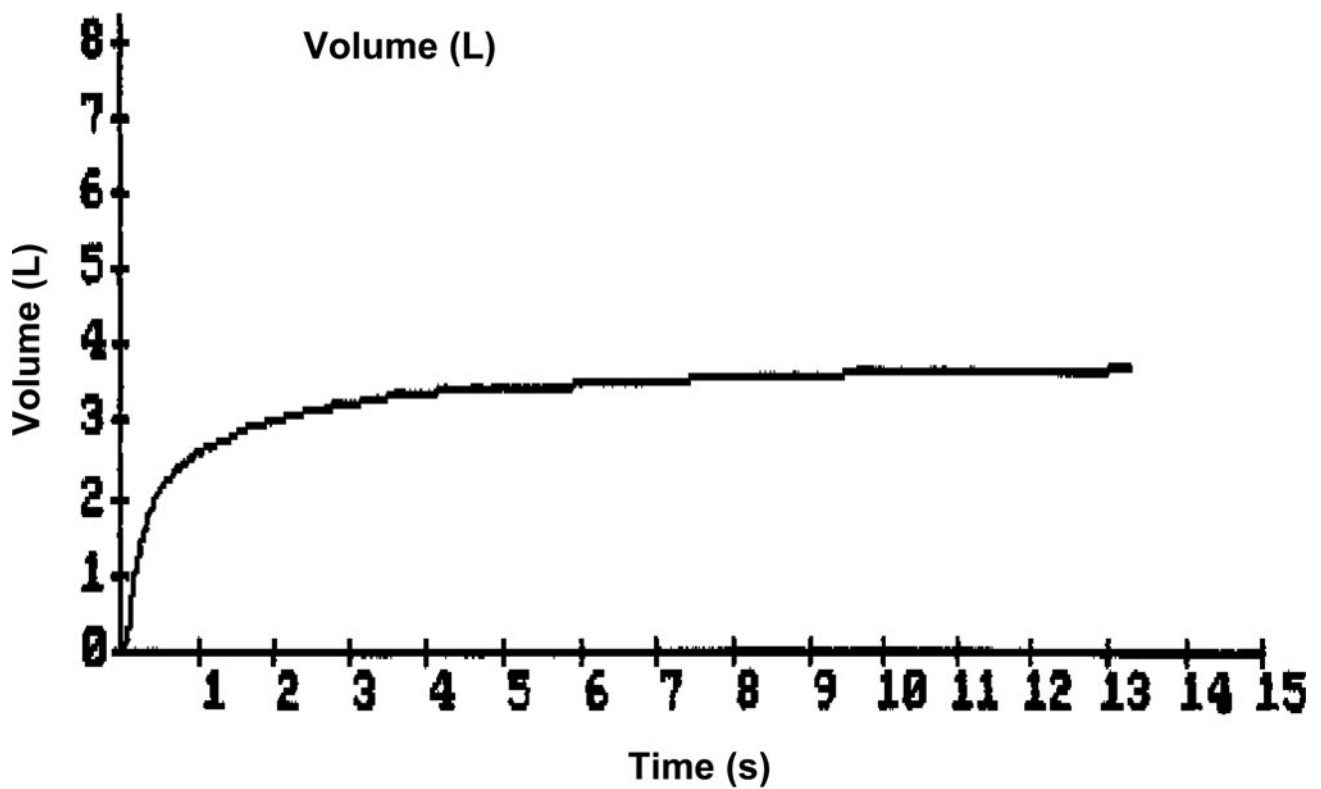
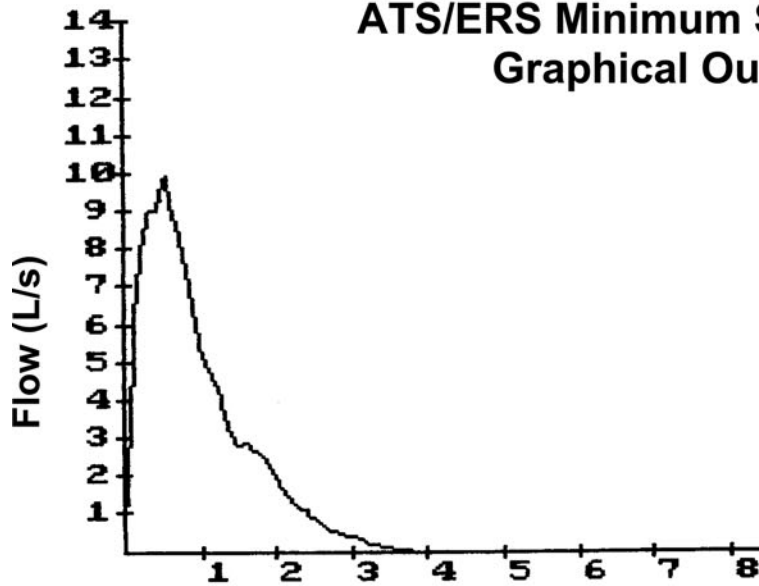
The committee thanks, first and foremost, the many members of the occupational health community who for decades have generously shared their interest, questions, and perspectives on occupational spirometry testing. Second, the committee thanks Drs John Hankinson and Philip Harber for their support and insightful comments during the development of this position statement. This guidance statement was reviewed by ACOEM Council of Scientific Advisors, and approved by ACOEM Board of Directors on January 23, 2010.

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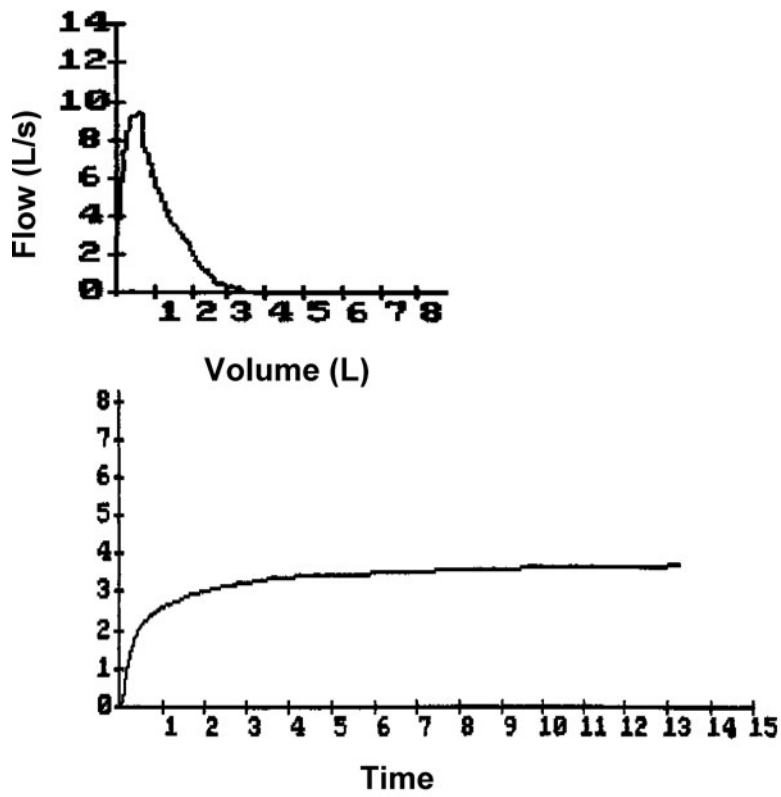
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APPENDIX ATS/ERS Minimum Size Hardcopy Graphical Output *



- Volume Scale ≥ 10 mm/ L
 - Flow Scale ≥ 5 mm/ L/s
 - Time Scale ≥ 10 mm/ s
- * Complies with ANSI ISO 25672 aspect ratio requirements.

ATS/ERS Minimum Size Instrument Display *



- Volume Scale ≥ 5 mm/ L
 - Flow Scale ≥ 2.5 mm/ L/s
 - Time Scale ≥ 5 mm/ s
- * Complies with ANSI ISO 25672 aspect ratio requirements.