

## Standardization of Spirometry 2019 Update

### An Official American Thoracic Society and European Respiratory Society Technical Statement: Executive Summary

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**Background:** Spirometry is the most common pulmonary function test. It is widely used in the assessment of lung function to provide objective information used in the diagnosis of lung diseases and monitoring lung health. In 2005, the American Thoracic Society and the European Respiratory Society jointly adopted technical standards for conducting spirometry. Improvements in instrumentation and computational capabilities, together with new research studies and enhanced quality assurance approaches, have led to the need to update the 2005 technical standards for spirometry to take full advantage of current technical capabilities.

**Methods:** This spirometry technical standards document was developed by an international joint task force, appointed by the American Thoracic Society and the European Respiratory Society, with expertise in conducting and analyzing pulmonary function tests, laboratory quality assurance, and developing international standards. A comprehensive review of published evidence was performed. A patient survey was developed to capture patients' experiences.

**Results:** Revisions to the 2005 technical standards for spirometry were made, including the addition of factors that were not previously considered. Evidence to support the revisions was cited when applicable. The experience and expertise of task force members were used to develop recommended best practices.

**Conclusions:** This document is an executive summary of the standards and consensus recommendations that are presented for manufacturers, clinicians, operators, and researchers with the aims of increasing the accuracy, precision, and quality of spirometric measurements and improving the patient experience. A comprehensive guide to aid in the implementation of these standards was developed as an online supplement.

**Keywords:** spirometry; spirometer; pulmonary function; technical standards

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**Overview**

This document is an executive summary of the update of the 2005 American Thoracic Society (ATS) and European Respiratory Society (ERS) standardization of spirometry (1), which in turn built on a wealth of previous work. Improvements in instrumentation and computational capabilities, together with new research studies and enhanced quality assurance approaches, have led to the need to update the 2005 technical standards for spirometry to take full advantage of current technical capabilities and evolving best practices. The updated spirometry standards cover equipment specifications, patient-related procedures, quality control, and data reporting. The principal measurements are FEV<sub>1</sub> and FVC. A comprehensive guide to aid in the implementation of these standards was developed as an online supplement.

**Key Updates**

- A new list of relative contraindications was added.
- Spirometers are now required to meet International Organization for Standardization (ISO) 26782 standards, but with a maximum permissible accuracy error of ±2.5%.
- Device quality assurance procedures were updated.
- Operator training as well as attainment and maintenance of competency were addressed.
- The list of activities that patients should avoid before testing was updated.
- There is a focus on the use of devices that measure both expiration and inspiration.
- Maneuver acceptability and repeatability criteria were updated. The end of forced expiration (EOFE) was redefined.
- Requirements for spirometry systems to provide uniform cues and feedback to the operator were added.
- New withholding times for bronchodilators before bronchodilator responsiveness testing were developed.

- A new grading system for assessment of spirometry quality was developed.
- Standardized operator feedback options that promote synoptic reporting were developed.
- Preliminary findings from an international patient survey were presented.

**Methods**

The ATS and the ERS approved a joint task force to update the 2005 spirometry standards (1). Task force members reviewed abstracts of 23,363 publications containing various terms related to spirometry published from 2004 to 2018 (Section E3 in the online supplement). All manufacturers of spirometry equipment were sent a survey requesting equipment specifications. An international survey of patients eliciting their experience in spirometry testing was conducted through the European Lung Foundation. The recommendations in this document represent a consensus of task force members in regard to the evidence available for various aspects of spirometric measurement and otherwise reflects the expert opinion of the task force members for areas in which peer-reviewed evidence was either not available or incomplete.

The major changes in the 2019 standards are described below. The most significant changes were for the forced expiratory VC maneuver. Minor changes were made for the slow VC maneuver, which are not covered in this summary. In this document, “operator” is the person conducting the test; the term “patient” is used for the person being tested, recognizing that not all persons will be patients; and “maneuver” is the term used for the inspiratory and expiratory VC excursions. The 2019 revision also includes updates of applicable sections of the 2005 ATS/ERS general considerations for lung function testing document (2).

**The Patient Experience**

To gather information regarding patients’ experiences and to identify problems faced by patients who have performed spirometry, an online survey completed by 1,760 spirometry patients from 52 countries was conducted in August and September 2018 by the European Lung Foundation. Patients reported the need for more information about spirometry before the test, including medication withholding. Eighty percent of respondents found the degree of difficulty to be mostly acceptable or completely acceptable. Even so, 31% considered the statement “To keep blowing even though you do not feel anything is coming out” to describe a moderate or serious issue. This could be addressed by having a digital or analog display of flow on the screen to give patients feedback on their expiratory rate during the maneuver. Key messages from the survey are provided in Section E2. Full results of the survey will be forthcoming in a future publication.

**Relative Contraindications**

The forced expiratory maneuver used in spirometry will result in increased intrathoracic, intraabdominal, and intracranial pressures (3–7). Table 1 lists relative contraindications for spirometry. The previous contraindication of spirometry testing within 1 month of a myocardial infarction (2) was changed to 1 week.

**Equipment**

The major changes are that the requirement of using the ATS waveforms to test spirometer performance (1) was replaced, and the accuracy requirement was tightened to ±2.5%. All spirometers must meet the standards contained in the current update of International Organization for Standardization (ISO) 26782 (8).

**Table 1.** Relative Contraindications for Spirometry

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Due to increases in myocardial demand or changes in blood pressure
Acute myocardial infarction within 1 wk
Systemic hypotension or severe hypertension
Significant atrial/ventricular arrhythmia
Noncompensated heart failure
Uncontrolled pulmonary hypertension
Acute cor pulmonale
Clinically unstable pulmonary embolism
History of syncope related to forced expiration/cough
Due to increases in intracranial/intraocular pressure
Cerebral aneurysm
Brain surgery within 4 wk
Recent concussion with continuing symptoms
Eye surgery within 1 wk
Due to increases in sinus and middle ear pressures
Sinus surgery or middle ear surgery or infection within 1 wk
Due to increases in intrathoracic and intraabdominal pressure
Presence of pneumothorax
Thoracic surgery within 4 wk
Abdominal surgery within 4 wk
Late-term pregnancy
Infection control issues
Active or suspected transmissible respiratory or systemic infection, including tuberculosis
Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding

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Spirometry should be discontinued if the patient experiences pain during the maneuver. Relative contraindications do not preclude spirometry but should be considered when ordering spirometry. The decision to conduct spirometry is determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits of spirometry for the particular patient. Potential contraindications should be included in the request form for spirometry.

Notwithstanding the ISO 26782, Section 7, performance requirements of being within  $\pm 3.0\%$  for accuracy, linearity, and repeatability, spirometry equipment must have a maximum permissible error less than or equal to  $\pm 2.5\%$  when tested with a 3-L calibration syringe and when using the test profiles of ISO 26782, Section 7, Annex C. Key aspects of equipment quality assurance are summarized in Table 2.

A 3-L syringe used to verify the volume calibration must have an accuracy of  $\pm 0.5\%$  of full scale. Calibration syringes must have a monthly leak test at more than one volume up to their maximum; this can be done by attempting to empty or fill them with the outlet corked (9). Spirometer calibration verifications must be undertaken at least daily using a 3-L syringe cycled at least three times to give a range of flows varying between 0.5 and 12 L/s (with 3-L injection times between 0.5 and 6 s). The volume at each flow must meet the accuracy requirement of  $\pm 3\%$  ( $\pm 2.5\%$  for spirometers plus  $\pm 0.5\%$  for calibration syringes).

### Operator Details

More emphasis on the roles, responsibilities, and training of the operator was added. It is the responsibility of the operator to observe and engage with the patient to achieve optimal results, which requires a combination of training and experience. Training courses for conducting quality spirometry testing are available in many countries, which has led to operators following ATS/ERS standards (10–14), but short-term follow-up and supplementary training are important to maintain quality (15, 16). Operator training as well as attainment and maintenance of competency must be integrated in any spirometry testing service (17). Changes in the 2019 standards include requirements for operator comments and for the spirometry system to provide feedback to the operator.

### Patient Details

The patient's age, birth sex, height, and weight are recorded. It is preferable to

calculate age using the date of birth and the date of the test, including in jurisdictions where birth dates may only be recorded to the nearest month. Age must be reported in years to one decimal place. Height in centimeters to one decimal place (18) and weight to the nearest 0.5 kg must be recorded; these may also be expressed in inches and pounds in jurisdictions still using those measures. Body mass index should be calculated as  $\text{kg/m}^2$ . The height must be measured without shoes, with the feet together, standing as tall as possible with the eyes level and looking straight ahead, and the back flush against a wall or stadiometer. For patients unable to stand erect, height may be estimated using ulna length (preferred for children) (19) or arm span (20, 21) (see Section E4), recognizing that there are sex, age, and ethnic differences in such estimates. Ulna length should be measured with calipers to avoid error introduced using a tape measure. In persons aged 25 years or older, for whom a reliable height measurement has been made previously in the same facility, remeasuring height at subsequent visits within 1 year may not be necessary.

### Patient Preparation

Patients should avoid the activities listed in Table 3, and these requirements should be given to the patient at the time of making the appointment. On arrival, all of these points must be checked, and any deviations from them must be recorded. Instructions on withholding medications should be given to the patient at the time of making the appointment (see BRONCHODILATOR RESPONSIVENESS TESTING).

### FEV<sub>1</sub> and FVC Maneuver

#### Test Procedure

Whereas previous guidelines were more focused on volume measurement devices using the expiration-only technique, this revision focuses more on spirometers measuring inspiratory and expiratory flow. The principal measurements are FEV<sub>1</sub> and FVC. There are four distinct phases of the FVC maneuver: 1) maximal inspiration, 2) a "blast" of expiration, 3) continued complete expiration for a maximum of 15 seconds, and 4) inspiration at maximal flow back to maximum lung volume. The operator must demonstrate the appropriate

**Table 2.** Equipment Quality Assurance (for Both Volume- and Flow-based Sensors)**Spirometer**

- Daily calibration verification at low, medium, and high flow: If the calibration verification fails, check for and remediate problems and repeat calibration verification
- If an in-line filter is used in spirometry testing, then it must also be used during recalibrations and verifications
- Recalibrate the spirometer both after failed calibration verification and at intervals specified by the manufacturer
- If the change in calibration factor is  $\geq 6\%$  or varies by more than  $\pm 2$  SD from the mean, inspect and, if necessary, clean the spirometer according to the manufacturer's instructions; check for errors and recalibrate the spirometer
- Perform routine checks and maintenance at intervals specified by the manufacturer

**3-L calibration syringe**

- Daily inspection for displacement of the piston stop
- Daily check for smooth operation of the syringe with no sticking or catching
- Accuracy of  $\pm 0.015$  L verified by manufacturer on delivery and at intervals recommended by the manufacturer
- Monthly syringe leak test

**Documentation**

- A log of all quality control findings, repairs and adjustments, and hardware and software updates
- Verification of reference value calculations after software updates

technique and follow the procedure described in Table 4.

With appropriate coaching, children as young as 2.5 years old with normal cognitive and neuromotor function are able to perform acceptable spirometry (22). The operators who are involved in the pulmonary function testing of young children should be specifically trained and competent for working with this population (22, 23).

**Within-Maneuver Evaluation**

The revised standards focus more on acceptability of the individual measurements of FEV<sub>1</sub> and FVC than on the maneuver as a whole. There are new objective methods to determine which FEV<sub>1</sub> and FVC measurements are acceptable and which technically unacceptable measurements could still be clinically useful (i.e., "usable") (Table 5). The criteria described below were

developed as objective measures to determine whether a maximal effort was achieved. In some cases, maneuvers that do not meet all of the criteria may be the best that the patient is able to do on this occasion, and usable rather than acceptable data are obtained.

The start of forced expiration, for the purpose of timing, is determined by the back-extrapolation method (1, 8). The back-extrapolated volume (BEV) is the volume of gas that has been expired from maximal lung volume to Time 0 and is included in the FEV<sub>1</sub> and FVC measurements (see Figure 1 of the full standards article). To achieve an accurate Time 0 and ensure that the FEV<sub>1</sub> comes from a maximal effort, the BEV must be  $< 5\%$  of the FVC or 0.100 L, whichever is greater (24, 25). The 0.100-L tolerance is a reduction from the 0.150-L tolerance in the 2005 standards (1).

**Table 3.** Activities That Should Be Avoided before Lung Function Testing

- Smoking and/or vaping and/or water pipe use within 1 h before testing (to avoid acute bronchoconstriction due to smoke inhalation)
- Consuming intoxicants within 8 h before testing (to avoid problems in coordination, comprehension, and physical ability)
- Performing vigorous exercise within 1 h before testing (to avoid potential exercise-induced bronchoconstriction)
- Wearing clothing that substantially restricts full chest and abdominal expansion (to avoid external restrictions on lung function)

**End of forced expiration.** Previous standards used the term "end of test" and the abbreviation "EOT" to denote end of forced expiration (EOFE). These standards stress the importance of a maximal inspiration after the forced expiration. As such, the end of forced expiration is not the end of the maneuver, and hence the term EOFE is used.

Recognizing a satisfactory EOFE is important to ensure that a true FVC has been achieved. Achieving one of the following three recommended indicators of EOFE is required (Figure 1):

1. There is less than a 0.025-L change in volume for at least 1 second (a "plateau"). This is the most reliable indicator of complete expiration. The system must provide both an indicator on the real-time display and an audio alert—a single beep—when this criterion has been reached. Note that a closure of the glottis may prematurely terminate a maneuver, hence rendering it unacceptable for FVC, even when the apparent duration of expiration is much longer.

OR

2. The patient has achieved a forced expiratory time (FET) of 15 seconds. The system must provide both an indicator on the real-time display and an audio alert—a double beep—when this criterion has been reached. For patients with airway obstruction or older patients, longer FETs are frequently achieved; however, FETs longer than 15 seconds will rarely change clinical decisions (1). A study of adults (mean age, 67 yr) found that more than 95% of obstructed patients had an FET shorter than 15 seconds and more than 95% of normal subjects had an FET shorter than 11 seconds (26). Multiple prolonged expirations are seldom justified and may cause light-headedness, syncope, undue fatigue, and unnecessary discomfort.

OR

3. The patient cannot expire long enough to achieve a plateau (e.g., children with high elastic recoil or patients with restrictive lung disease). In this case, the measure of whether EOFE has been reached is for the patient to repeatedly achieve the same FVC. For within-maneuver acceptability, the FVC must be greater than or within the repeatability tolerance of the greatest FVC observed before this maneuver in the current



**Table 4.** Procedures for FVC Maneuvers**Wash hands\*** (or use an approved hand sanitizer)**Prepare the patient**

- Dispense hand sanitizer for the patient
- Confirm patient identification, age, birth sex, ethnicity, etc.
- Measure weight and height without shoes
- Ask about activities listed in Table 3, medication use, and any relative contraindications flagged on the requisition; note respiratory symptoms

**Instruct and demonstrate the test**

- Position of the mouthpiece and noseclip
- Correct posture with head slightly elevated
- Inspire rapidly until completely full
- Expire with maximal effort until completely empty
- Inspire with maximal effort until completely full
- Confirm that patient understands the instructions and is willing to comply

**Perform maneuver**

- Have patient assume the correct posture
- Attach noseclip, place mouthpiece in mouth, and close lips around the mouthpiece
- Breathe normally
- Inspire completely and rapidly with a pause of  $\leq 2$  s at TLC
- Expire with maximal effort until no more air can be expelled while maintaining an upright posture
- Inspire with maximal effort until completely full
- Repeat instructions as necessary, coaching vigorously
- Repeat for a minimum of three maneuvers, usually no more than eight for adults
- Check FEV<sub>1</sub> and FVC repeatability and perform more maneuvers as necessary

**Perform maneuver (expiration-only devices)**

- Have patient assume the correct posture
- Attach noseclip
- Inspire completely and rapidly with a pause of  $\leq 2$  s at TLC
- Place mouthpiece in mouth and close lips around the mouthpiece
- Expire with maximal effort until no more air can be expelled while maintaining an upright posture
- Repeat instructions as necessary, coaching vigorously
- Repeat for a minimum of three maneuvers, usually no more than eight for adults
- Check FEV<sub>1</sub> and FVC repeatability and perform more maneuvers as necessary

\*Additional steps may be required by local infection control policies. Using disposable gloves does not eliminate the need for hand washing or sanitizing, but if gloves are used, a new pair is required for each patient.

testing set. If the first maneuver of either the prebronchodilator testing set or post-bronchodilator testing set does not have a plateau and FET <15 seconds, it provisionally meets this EOFE criterion for acceptability, subject to comparison with the FVC from subsequent maneuvers. It becomes acceptable if it is within the repeatability tolerance of or is greater than a subsequent FVC. Hence, for the prebronchodilator and post-bronchodilator testing sets analyzed separately, all FVC values from maneuvers without a plateau and FET shorter than 15 seconds that are within the repeatability tolerance of the maximum FVC in that set are judged to have met the EOFE acceptability criterion. Although patients should be

strongly encouraged to achieve their maximal effort, the operator should be alert to any indication that the patient is experiencing discomfort and should terminate the maneuver if a patient is significantly uncomfortable or is approaching syncope.

Maneuvers that do not meet any of the EOFE acceptability criteria will not provide acceptable FVC measures. However, an acceptable FEV<sub>1</sub> may be obtained from a maneuver with early termination after 1 second. For children aged 6 years or younger, an acceptable FEV<sub>0.75</sub> may be obtained from a maneuver with early termination after 0.75 seconds.

Note that there is no requirement for a minimum FET. The 2005 ATS/ERS requirement of a minimum FET (1) resulted

in some valid maneuvers being classified as inadequate (27–29). In a study of 1,631 healthy children age 10–18 years, only 18% met the 2005 minimum FET in maneuvers that were visually judged to be acceptable (30). However, eliminating a minimum FET comes at the cost of requiring increased vigilance by the operator and the interpreter in the assessment of whether expiration was complete or there was early termination.

If the volume of the maximal inspiration (i.e., forced inspiratory VC [FIVC]) after EOFE is greater than FVC, this indicates that the patient did not start the maneuver from TLC. FEV<sub>1</sub> and FVC measurements are not acceptable if FIVC – FVC is >0.100 L or 5% of FVC, whichever is greater, but they may be usable.

Glottic closure or early termination, such as inspiration or coming off the mouthpiece, renders FVC unacceptable. If glottic closure or cough occurs in the first 1 second, then FEV<sub>1</sub> is unacceptable and unusable. A similar termination in the first 0.75 seconds renders FEV<sub>0.75</sub> (the forced expiratory volume in the first 0.75 s) unacceptable and unusable.

**Operator feedback.** The spirometry system software must provide explicit feedback to the operator at the completion of each maneuver indicating FEV<sub>1</sub> and FVC acceptability. Sample warning messages and suggestions to correct the problems are provided in Section E6. The operator must have the ability to override the acceptability designation, because the operator may note a leak, a cough, inadequate inspiration or expiration, or a faulty zero-flow level that was not detected by the software.

Records of all maneuvers with FEV<sub>1</sub> and/or FVC that are acceptable or usable must be retained because, for some patients, their best performance yields only usable data. Examples of acceptable and unacceptable volume–time curves and corresponding flow–volume curves are provided in Figures E1–E12.

**Between-Maneuver Evaluation**

The goal of the test session is to achieve a minimum of three acceptable FEV<sub>1</sub> and three acceptable FVC measurements. This is a departure from previous standards, which required three maneuvers in which both FEV<sub>1</sub> and FVC were acceptable. Repeatability is achieved when the difference between the largest and the next largest FVC is  $\leq 0.150$  L for patients older than 6 years of age (31) and  $\leq 0.100$  L or

**Table 5.** Summary of Acceptability, Usability, and Repeatability Criteria for FEV<sub>1</sub> and FVC

Acceptability and Usability Criterion	Required for Acceptability		Required for Usability	
	FEV <sub>1</sub>	FVC	FEV <sub>1</sub>	FVC
Must have BEV ≤5% of FVC or 0.100 L, whichever is greater	Yes	Yes	Yes	Yes
Must have no evidence of a faulty zero-flow setting	Yes	Yes	Yes	Yes
Must have no cough in the first second of expiration*	Yes	No	Yes	No
Must have no glottic closure in the first second of expiration*	Yes	Yes	Yes	Yes
Must have no glottic closure after 1 s of expiration	No	Yes	No	No
Must achieve one of these three EOFE indicators:	No	Yes	No	No
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 <sup>†</sup>				
Must have no evidence of obstructed mouthpiece or spirometer	Yes	Yes	No	No
Must have no evidence of a leak	Yes	Yes	No	No
If the maximal inspiration after EOFE is greater than FVC, then FVC – FVC must be ≤0.100 L or 5% of FVC, whichever is greater <sup>‡</sup>	Yes	Yes	No	No

**Repeatability criteria** (applied to acceptable FVC and FEV<sub>1</sub> values)

Age >6 yr: The difference between the two largest FVC values must be ≤0.150 L, and the difference between the two largest FEV<sub>1</sub> values must be ≤0.150 L

Age ≤6 yr: The difference between the two largest FVC values must be ≤0.100 L or 10% of the highest value, whichever is greater, and the difference between the two largest FEV<sub>1</sub> values must be ≤0.100 L or 10% of the highest value, whichever is greater

*Definition of abbreviations:* BEV = back-extrapolated volume; EOFE = end of forced expiration; FEV<sub>0.75</sub> = forced expiratory volume in the first 0.75 seconds; FVC = forced inspiratory VC.

The grading system (Table 7) will inform the interpreter if values are reported from usable maneuvers not meeting all acceptability criteria.

\*For children aged 6 years or younger, must have at least 0.75 seconds of expiration without glottic closure or cough for acceptable or usable measurement of FEV<sub>0.75</sub>.

<sup>†</sup>Occurs when the patient cannot expire long enough to achieve a plateau (e.g., children with high elastic recoil or patients with restrictive lung disease) or the patient inspires or comes off the mouthpiece before a plateau. For within-maneuver acceptability, the FVC must be larger than or within the repeatability tolerance of the largest FVC observed before this maneuver within the current prebronchodilator or the current post-bronchodilator testing set.

<sup>‡</sup>Although the performance of a maximal forced inspiration is strongly recommended, its absence does not preclude a maneuver from being judged acceptable, unless extrathoracic obstruction is specifically being investigated.

10% of the highest value, whichever is greater, for those aged 6 years or younger (22, 32), and the difference between the largest and the next largest FEV<sub>1</sub> is ≤0.150 L for those older than 6 years of age and ≤0.100 L or 10% of the highest value, whichever is greater, for those aged 6 years or younger. If these criteria are not met in three maneuvers, additional trials must be attempted, up to eight maneuvers in adults, although more may be done in children (Figure 2).

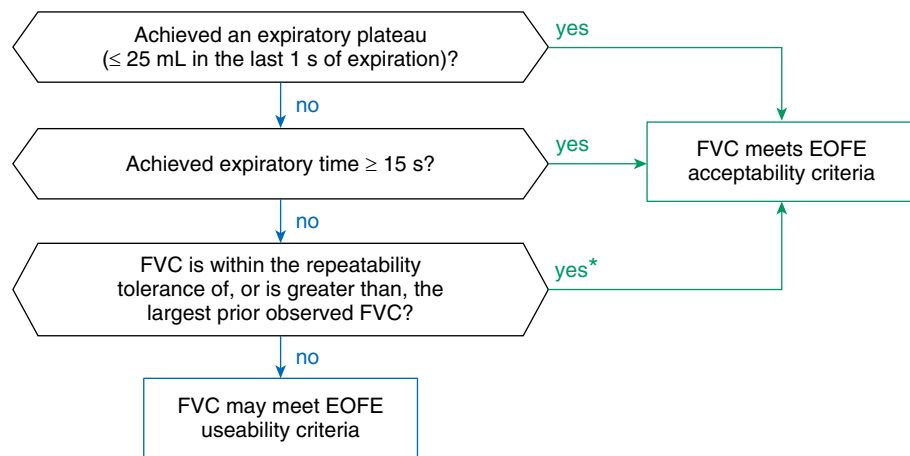
Achieving repeatable results is the best indicator that the patient performed the maximal FEV<sub>1</sub> and FVC that she or he was capable of doing. The degree of repeatability, which is quantified in the grading system (see GRADING THE QUALITY OF THE TEST SESSION), drives the confidence level in the interpretation of the results.

**Bronchodilator Responsiveness Testing**

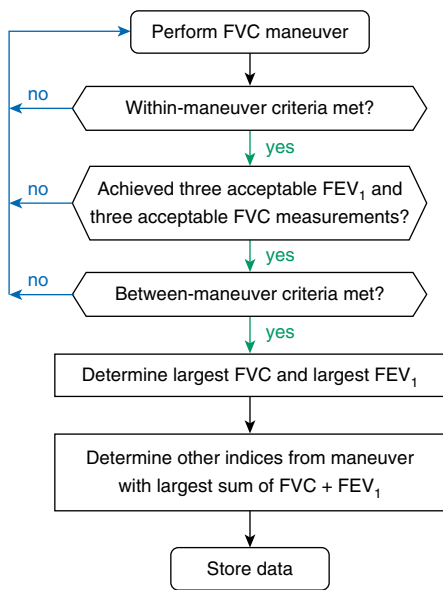
Previously, the term “reversibility testing” has been used, but the term

“bronchodilator responsiveness testing” is used in these standards to avoid the unwarranted inference that “reversibility” implies the complete elimination of airway obstruction (33). Bronchodilator

responsiveness testing is a determination of the degree of improvement of airflow in response to bronchodilator administration as measured by changes in FEV<sub>1</sub> and FVC. If bronchodilators are to be withheld,



**Figure 1.** Flowchart outlining the end of forced expiration (EOFE) acceptability criteria for FVC. \*If there are no prior observed FVC values in the current pre- or post-bronchodilator testing set, then the FVC provisionally meets EOFE acceptability criteria.



**Figure 2.** Flowchart outlining application of acceptability and repeatability criteria.

Table 6 lists suggested withholding times for various bronchodilators based on studies of the lasting bronchodilator effects of the various agents.

**Test Procedure**

The patient first performs prebronchodilator spirometry to achieve three acceptable FEV<sub>1</sub> and FVC measurements as described previously. Next, the bronchodilator is administered in the dose and by the method specified in the protocol for the spirometry facility (see Section E7 for examples). Three or more additional post-bronchodilator acceptable FEV<sub>1</sub> and FVC measurements are then obtained after the wait time specified in the facility protocol. Every facility conducting

bronchodilator responsiveness testing must have a written protocol for the test.

The ATS standardized report form (34) should be used as the default report form for spirometry systems. The default set of reference values for all ages should be the Global Lung Function Initiative reference equations (35), although other options may be provided. In addition to summary reports, the interpreter should have access to a report of all maneuvers within a testing session. The flow and/or volume data from each test session must be available for export with adequate information for the facility manager to extract results and plot volume–time and flow–volume graphs of each maneuver (Section E8). The system should also have the capability to export data to electronic medical records, both as .pdf file copies of the printed report and discrete data, using the Clinical Document Architecture Release 2 standard of HL7 International (36) or Fast Healthcare Interoperability Resources. Logical Observation Identifiers Names and Codes should be used to identify test data so that data captured in the electronic health record can be accessed and understood universally. A workshop at the ATS 2019 International Conference began the process of developing an interoperability roadmap to integrate pulmonary function data in electronic health records.

Operator comments are a key part of the report. The system must permit the operator to enter comments from a dropdown menu as well as free text. The facility manager should have the ability to edit the list of menu options. A list of standard operator comments is provided in Section E9.

**Grading the Quality of the Test Session**

Technical standards are designed to help attain the best result possible for each patient. Spirometry results are very dependent on patient cooperation. Maneuvers done at maximal lung volume with maximal effort are more repeatable than maneuvers that are done at submaximal lung volumes or with submaximal effort. Although there may be other indicators of submaximal spirometry, in general, the acceptability and repeatability criteria provided in this document are validated and objective (1, 32, 34, 37).

The grading system that is recommended by the ATS for spirometry reporting (34), which is a modified version of the system developed by Hankinson and colleagues (38) and expanded to include young children, should be used (Table 7). Grade “U” was added to denote “usable” values. FEV<sub>1</sub> and FVC are graded separately. The grading applies to the set of prebronchodilator maneuvers as a whole rather than individual maneuvers and is determined separately for the set of post-bronchodilator maneuvers.

This grading system informs the interpreter about the level of confidence that the spirometry results represent the best that the patient was able to do at the time of the test and the probability that an equivalent value would be achieved if the test were to be repeated. Some patients may not be able to meet the criteria for acceptability and repeatability that are necessary for grade A, but nevertheless, their results may be clinically useful. For example, the spirometry maneuver may trigger the cough reflex, and after the first one or two attempts, the patient may not be able to do another acceptable maneuver. In cases in which grades less than A are the best that can be achieved within the test session, the clinical judgment of the interpreter becomes a more important factor in the interpretation of the results. *Although some maneuvers may be acceptable or usable at grading levels lower than A, the overriding goal of the operator must be to always achieve the best possible testing quality for each patient.*

Patients who see the grade assigned to their values might erroneously assume that the grade applies to the health of their lungs. The operator should inform the patient that

**Table 6.** Bronchodilator Withholding Times

Bronchodilator Medication	Withholding Time
SABA (e.g., albuterol or salbutamol)	4–6 h
SAMA (e.g., ipratropium bromide)	12 h
LABA (e.g., formoterol or salmeterol)	24 h
Ultra-LABA (e.g., indacaterol, vilanterol, or olodaterol)	36 h
LAMA (e.g., tiotropium, umeclidinium, aclidinium, or glycopyrronium)	36–48 h

*Definition of abbreviations:* LABA=long-acting β<sub>2</sub>-agonist; LAMA=long-acting muscarinic antagonist; SABA=short-acting β<sub>2</sub>-agonist; SAMA=short-acting muscarinic antagonist. *Note:* Withholding times for post-bronchodilator testing are shorter than those for methacholine challenge testing (39) because the bronchoprotection provided by these agents lasts longer than their bronchodilation effects. In the case of dual bronchodilators, the withholding time for the longer-acting bronchodilator is used.

**Table 7.** Grading System for FEV<sub>1</sub> and FVC (Graded Separately)

Grade	Number of Measurements	Repeatability: Age >6 yr	Repeatability: Age ≤6 yr*
A	≥3 acceptable	Within 0.150 L	Within 0.100 L*
B	2 acceptable	Within 0.150 L	Within 0.100 L*
C	≥2 acceptable	Within 0.200 L	Within 0.150 L*
D	≥2 acceptable	Within 0.250 L	Within 0.200 L*
E	≥2 acceptable	>0.250 L	>0.200 L*
	OR 1 acceptable	N/A	N/A
U	0 acceptable AND ≥1 usable	N/A	N/A
F	0 acceptable and 0 usable	N/A	N/A

*Definition of abbreviation:* N/A = not applicable.

The repeatability grade is determined for the set of prebronchodilator maneuvers and the set of post-bronchodilator maneuvers separately. The repeatability criteria are applied to the differences between the two largest FVC values and the two largest FEV<sub>1</sub> values. Grade U indicates that only usable but not acceptable measurements were obtained. *Although some maneuvers may be acceptable or usable at grading levels lower than A, the overriding goal of the operator must be to always achieve the best possible testing quality for each patient.* Adapted from Reference 34.

\*Or 10% of the highest value, whichever is greater; applies for patients aged 6 years or younger only.

the grade refers to the consistency of their blows.

**Other**

There are new requirements for data storage (Section E8). Minor changes

were made to the measurement of slow VC and inspiratory capacity. The 2005 standards section on peak expiratory flow as a separate procedure was not included in this revision, because it can be measured from the spirometry maneuver. These standards emphasize the role of the

operator, and home monitoring or unattended spirometry is not included. The 2005 standards section on maximum voluntary ventilation was believed to belong in exercise testing standards and was not included in the update. ■

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