AMERICAN THORACIC SOCIETY DOCUMENTS

# Standardization of Spirometry 2019 Update

## An Official American Thoracic Society and European Respiratory Society Technical Statement

Brian L. Graham, Irene Steenbruggen, Martin R. Miller, Igor Z. Barjaktarevic, Brendan G. Cooper, Graham L. Hall, Teal S. Hallstrand, David A. Kaminsky, Kevin McCarthy, Meredith C. McCormack, Cristine E. Oropez, Margaret Rosenfeld, Sanja Stanojevic, Maureen P. Swanney†, and Bruce R. Thompson; on behalf of the American Thoracic Society and the European Respiratory Society

This official technical statement was approved by the American Thoracic Society and the European Respiratory Society September 2019

**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:** Standards and consensus recommendations 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

**Contents**

Overview
Key Updates
Introduction
Methods
The Patient Experience
Indications
Relative Contraindications
Laboratory Details

†Deceased February 17, 2019.

ORCID IDs: 0000-0003-1794-7682 (I.S.); 0000-0001-9971-5759 (M.R.M.); 0000-0002-8096-0858 (I.Z.B.); 0000-0003-0785-1038 (B.G.C.); 0000-0002-6217-9494 (G.L.H.); 0000-0002-5059-6872 (T.S.H.); 0000-0002-6515-8023 (D.A.K.); 0000-0003-1702-3201 (M.C.M.); 0000-0001-7931-8051 (S.S.); 0000-0002-5885-0652 (B.R.T.).

Supported by the American Thoracic Society and the European Respiratory Society.

An Executive Summary of this document is available at http://www.atsjournals.org/doi/suppl/10.1164/rccm.201908-1590ST.

You may print one copy of this document at no charge. However, if you require more than one copy, you must place a reprint order. Domestic reprint orders: amy.schriver@sheridan.com; international reprint orders: louisa.mott@springer.com.

Correspondence and requests for reprints should be addressed to Brian L. Graham, Ph.D., Division of Respirology, Critical Care and Sleep Medicine, University of Saskatchewan, 103 Hospital Drive, Saskatoon, SK, S7N 0W8 Canada. E-mail: brian.graham@usask.ca.

This article has an online supplement, which is accessible from this issue's table of contents at www.atsjournals.org.

Am J Respir Crit Care Med Vol 200, Iss 8, pp e70–e88, Oct 15, 2019
Copyright © 2019 by the American Thoracic Society
DOI: 10.1164/rccm.201908-1590ST
Internet address: www.atsjournals.org

Hygiene and Infection Control
Equipment
  Display
  BTPS Adjustment
Device Quality Assurance
Operator Details
Patient Details
  Patient Preparation
$FEV_1$ and FVC Maneuver
  Test Procedure
  Within-Maneuver Evaluation
  Between-Maneuver Evaluation
  Maximum Number of Maneuvers
Bronchodilator Responsiveness Testing
  Test Procedure
Reported Values
  Other Derived Indices
Grading the Quality of the Test Session
VC and Inspiratory Capacity Maneuver
  Equipment
  Test Procedure
Further Studies
  Other Potential Analyses


## Overview

This document is an 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 (2–6). Additional standards have been developed for occupational surveillance (7) and for preschool children (8). 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. This technical report covers definitions, equipment specifications, patient-related procedures, quality control, and data reporting. A comprehensive guide to aid in the implementation of these standards was developed as an online supplement. A summary of the primary changes in this update is provided in Table E1 in the 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 derived from an international patient survey were presented.

## Introduction

Spirometry is a physiological test that measures the maximal volume of air that an individual can inspire and expire with maximal effort. The primary signal measured in spirometry is either volume or flow as a function of time. The most relevant measurements discussed in this document are the FVC, which is the volume delivered during an expiration made as forcefully and completely as possible starting from full inspiration, and the $FEV_1$, which is the expiratory volume in the first second of an FVC maneuver. These standards also apply to measurements of $FEV_1$ in airway responsiveness testing and exercise testing. Other spirometric variables derived from the FVC maneuver are also addressed, as well as the measurement of VC from a slow maneuver.

In this document, the "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 term "must" is used to indicate a requirement for meeting the standards, and "should" is used to indicate actions that may not be mandatory but are considered to be best practices.

These standards are the minimum criteria that must be met for clinical spirometry, which may not be sufficient for all settings, such as research or occupational surveillance (7). The spirometry facility manager is also responsible for following local regulations, which may have additional requirements. As manufacturers continue to improve spirometric instrumentation and as new technology is implemented, it is expected that new systems will meet and, in many cases, exceed these new standards. Standards that are developed and updated from time to time should not limit the quest for continual improvement in the quality of lung function measurements and innovation in applying new technology (9).

This revision also includes updates of applicable sections of the 2005 ATS/ERS general considerations for lung function testing document (10). Although these standards apply in primary care, some studies have shown that standards are often not met in primary care (11, 12). However, in studies of patients with asthma and/or chronic obstructive pulmonary disease (COPD), office spirometry was accurate and reliable when compared with laboratory-based spirometry (13–15), demonstrating that competent operators using equipment that meets ATS/ERS standards can meet the spirometry acceptability criteria in the primary care setting.

## Methods

An application was submitted for a joint ATS and ERS task force to update the 2005 spirometry standards (1). The task force membership and co-chairs were approved by the ATS and the ERS. Task force members were scientists and physicians with experience in international guidelines and standards; clinical experience in routine lung function testing; and specialist knowledge of spirometry, including research publications. All potential conflicts of interest were disclosed and managed according to the rules and procedures of the ATS and the ERS. A search in the

MEDLINE database (using PubMed) for publications containing various terms related to spirometry published from 2004 to 2018 yielded 23,368 citations (search terms listed in Section E3). Task force members reviewed the abstracts and identified 190 as directly relevant to the project and a further 382 as potentially relevant. New publications were monitored after the initial search, and twelve 2018 and 2019 references are included. All manufacturers of spirometry equipment were sent a survey requesting equipment specifications. The task force also reviewed equipment specifications published on the manufacturers' websites. An international survey of patients was conducted through the European Lung Foundation to elicit their experience in spirometry testing. Using the 2005 standards as the base document, revisions and additions were made on a consensus basis. The recommendations in this document represent a consensus of task force members in regard to the evidence available for various aspects of spirometric measurement (as cited in the document) and otherwise reflects the expert opinion of the task force members for areas in which peer-reviewed evidence was either not available or incomplete. Constraints on the development of these standards are listed in Section E12.

## 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 an analog or digital display of flow in ml/s on the screen to give patients feedback on their expiratory rate during the maneuver. Key messages from the survey are provided in Section E4. Full results of the survey will be forthcoming in a future publication.

## Indications

Spirometry is fundamental in the assessment of general respiratory health. Spirometry enables measuring the effect of a disease on lung function, assessing airway responsiveness, monitoring disease course or the result of therapeutic interventions, assessing preoperative risk, and determining a prognosis for many pulmonary conditions. Spirometry is a valuable tool that provides important information to clinicians which is used together with other physical findings, symptoms, and history to reach a diagnosis. Common indications for spirometry are given in Table 1.

## Relative Contraindications

Performing spirometry can be physically demanding. The forced expiratory maneuver used in spirometry increases intrathoracic, intraabdominal, and intracranial pressures (16–20). Potential risks of spirometry are primarily related to maximal pressures generated in the thorax and their impact on abdominal and thoracic organs, venous return and systemic blood pressure, and expansion of the chest wall and lung. The physical effort required can increase myocardial demand. Caution must be used for patients with medical conditions that could be adversely affected by these physiological consequences (Table 2). Although such risks are likely to be minimal for spirometry in most patients (21), the potential risks associated with testing should always be weighed against the benefit of obtaining information about lung function (16, 17, 22). Spirometry should be discontinued if the patient experiences pain during the maneuver. Patients with potential contraindications that would prevent testing in the primary care setting may be tested in a pulmonary function laboratory where operators are more experienced and there may be access to emergency care if needed. Furthermore, because spirometry requires the active participation of the patient, inability to understand directions or unwillingness to follow the directions of the operator will usually lead to submaximal test results.

A 20-year review of 186,000 pulmonary function tests in a tertiary institution found that patient safety incidents occurred in 5 of every 10,000 routine pulmonary function tests (excluding exercise and provocation tests) with generally low risk of harm (21). Cardiopulmonary incidents, primarily syncope, were the most common finding. A study found that 10% of patients having maximal cardiopulmonary exercise tests had simple, self-limited arrhythmias induced by spirometry (23). No adverse effects were reported in spirometry conducted in studies of 56 and 230 (24, 25) patients with abdominal aortic aneurysms from 5 to 13 cm in size and in 519 patients with thoracic aortic aneurysms from 5 to 8 cm in size (26).

## Laboratory Details

Ambient temperature, barometric pressure, and time of day must be recorded. Temperature is an important variable in most pulmonary function tests and is sometimes measured directly by the instrument. The way in which it is measured and used may vary from instrument to instrument (e.g., a simple thermometer or an internal thermistor). Regardless of the method used, the operator should confirm the accuracy of temperature measurements, and the manufacturer should describe or provide a clear mechanism for checking the accuracy of instrument temperature measurements. Spirometers that require a barometric pressure measurement should have a barometric pressure sensor or the ability to calculate mean barometric pressure using altitude above sea level (27).

Testing should preferably occur in a quiet and comfortable environment that is separated from the waiting room and other patients being tested. Drinking water should be available. Tissues or paper towels should be offered to help patients deal with secretions. The patient should be seated erect, with shoulders slightly back and chin slightly elevated. A chair with arms (to prevent falling sideways should syncope occur), without wheels, and with a height adjustment so that the feet are flat on the floor should be used. A smaller chair or a raised footstool should be provided for children and small adults. For the maneuvers described below, a noseclip or manual occlusion of the nostrils should be used. If testing is undertaken with the

**Table 1.** Indications for Spirometry

| |
|---|
| Diagnosis |
| To evaluate symptoms, signs, or abnormal laboratory test results |
| To measure the physiologic effect of disease or disorder |
| To screen individuals at risk of having pulmonary disease |
| To assess preoperative risk |
| To assess prognosis |
| Monitoring |
| To assess response to therapeutic intervention |
| To monitor disease progression |
| To monitor patients for exacerbations of disease and recovery from exacerbations |
| To monitor people for adverse effects of exposure to injurious agents |
| To watch for adverse reactions to drugs with known pulmonary toxicity |
| Disability/impairment evaluations |
| To assess patients as part of a rehabilitation program |
| To assess risks as part of an insurance evaluation |
| To assess individuals for legal reasons |
| Other |
| Research and clinical trials |
| Epidemiological surveys |
| Derivation of reference equations |
| Preemployment and lung health monitoring for at-risk occupations |
| To assess health status before beginning at-risk physical activities |

patient in another position, this must be documented in the report. Tests done while standing are similar to sitting in studies of adults (28), obesity (29), and children (30). Fowler's position (elevated head and torso) yields higher values than supine or Crook's position (knees raised) (31). In most studies involving healthy subjects or patients with lung, heart, neuromuscular disease, or obesity, $FEV_1$ and FVC were higher in more erect positions, whereas for subjects with tetraplegic spinal cord injury, FVC and $FEV_1$ were higher in supine than while sitting (32).

## Hygiene and Infection Control

The goal of infection control is to prevent the transmission of infection to patients and staff during pulmonary function testing (33, 34). The number of documented cases of infection transmission is very small, but the potential is real. Infection can be transmitted by direct contact with surfaces such as mouthpieces, noseclips, handheld spirometers, chair arms, and immediate proximal surfaces of valves or tubing. Indirect transmission occurs by aerosol droplets generated by the patient blowing into the equipment but also expelled into the air of the testing room between maneuvers.

The operator must wash her or his hands or use an approved hand sanitizer before contact with each new patient (35). 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. The patient should be given an approved hand disinfectant gel or wipe upon first entry into the testing station, because patients will be touching various surfaces, and many spirometers are handheld.

The use of disposable, in-line filters for spirometers has become standard practice in most facilities. Furthermore, the mouthpiece is usually an integral part of the filter and will reduce contamination of the spirometer. All disposable items, including filters, mouthpieces, noseclips, and gloves, must be disposed of at the end of the testing session.

To avoid operator exposure and cross-contamination, hands must be washed immediately after direct handling of mouthpieces, tubing, breathing valves, or interior spirometer surfaces. Gloves should be worn when handling potentially contaminated equipment and/or if the operator has any open cuts or sores on his or her hands.

Manufacturers must explicitly describe acceptable methods of cleaning and disinfecting their equipment, including recommended chemicals and concentrations, as well as safety precautions for the operator. Local infection control requirements, especially for at-risk populations such as patients with cystic fibrosis (36), may supersede both manufacturers' recommendations and those in this document.

Extra precautions should be taken for patients with, or suspected of having, tuberculosis, hemoptysis, oral lesions, or other known transmissible infectious diseases. Possible precautions include reserving equipment for the sole purpose of testing infected patients or testing such patients at the end of the workday to allow time for spirometer disassembly and disinfection and/or testing patients in their own rooms with adequate ventilation and appropriate protection for the operator. Hygiene processes are described in more detail in the *ATS Pulmonary Function Laboratory Management and Procedure Manual* (37).

## Equipment

Manufacturers must ensure that all spirometers meet the standards contained in the current update of ISO 26782 (38). The current update is ISO 26782:2009, last reviewed in 2016 and scheduled to be reviewed next in 2021. Although not explicitly stated in ISO 26782, it is not permissible to recalibrate a spirometer between the individual test profiles of Annex C of ISO 26782. Notwithstanding the ISO 26782, Section 7, performance requirements of being within $\pm 3.0\%$ for accuracy, linearity, and repeatability, spirometric equipment must have a maximum permissible error of $\pm 2.5\%$ when tested with a 3-L calibration syringe and when using the test profiles of ISO 26782, Section 7, Annex C. If future ISO 26782 revisions specify a maximum permissible error less than $\pm 2.5\%$, then the lower value must be used. A 2018 survey of spirometer manufacturers worldwide found that 17 of 19 respondents reported that the accuracy of their products was within $\pm 2\%$. A study of 7,497 calibration verifications of volume spirometers demonstrated the need for more stringent standards (39). Thirteen of 19 manufacturers responding to the survey were compliant with ISO 26782:2009. A study has questioned whether the previously recommended ATS standard waveforms were sufficient (40). For

**Table 2.** Relative Contraindications for Spirometry

| |
|---|
| 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 |

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.

digitization of the flow or volume signal, the sampling rate must be ⩾100 Hz (41) with a minimum resolution of 12 bits. The ERS/ATS standards for diffusing capacity (42) specify a volume accuracy of ±2%, but the flow range required for the diffusing capacity maneuver is smaller than that for spirometry, and the systems measuring diffusing capacity primarily use higher-grade instrumentation. Therefore, laboratories using such equipment are expected to exceed accuracy requirements for spirometry.

#### Display

For optimal quality control, both volume–time and flow–volume real-time displays are required, and operators must visually inspect the performance of each maneuver for quality assurance before proceeding with another maneuver. For the flow–volume graph, expiratory flow must be plotted upward, and expiratory volume must be plotted toward the right. A 2:1 aspect ratio must be maintained between the flow and volume scales; that is, 2 L/s of flow and 1 L of volume must be the same distance on their respective axes.

Displays of flow versus volume provide more detail than volume–time graphs for the first 1 second of the FVC maneuver. Because this portion of the maneuver, particularly the peak expiratory flow (PEF), is correlated with the pleural pressure during the maneuver, the flow–volume graph is useful to assess the magnitude of effort during the initial portions of the maneuver. The ability to overlay a series of flow–volume graphs registered at the point of maximal inspiration may be helpful in evaluating repeatability and detecting submaximal efforts. However, if the point of maximal inspiration varies between maneuvers, then the interpretation of these results is difficult because the flows at identical measured volumes are being achieved at different absolute lung volumes. In contrast, display of the FVC maneuver as a volume–time graph provides more detail for the latter part of the maneuver. In a display of multiple trials, the sequencing of the maneuvers should be apparent to the operator.

For the start of test display, the volume–time graph must begin at the point of maximum inspiration or 1 second before Time 0 (defined below), whichever occurs first. The display of the maneuver should continue to the end of the plateau (defined below) or the beginning of inspiration.

#### BTPS Adjustment

All spirometry outcomes must be reported at BTPS (body temperature, ambient barometric pressure, saturated with water vapor). The ambient temperature must always be recorded with an accuracy of ±1°C. In situations when the ambient air temperature is changing rapidly (>3°C in <30 min), continuous temperature corrections may be necessary (Section E5). Operators should be aware of potential problems with tests performed outside the range of ambient temperatures and barometric pressures specified by the manufacturer for their particular spirometer.

Changes in spirometer or flow sensor temperature can be a source of variability (43). Spirometer temperature should be measured and not assumed to be constant, even over the course of one testing session. For volume spirometers, errors up to 6% in $FEV_1$ and FVC can occur if ambient temperature is used instead of internal temperature of volume spirometers (44). Therefore, when using volume spirometers, the temperature inside the spirometer should be measured for each breathing maneuver.

## Device Quality Assurance

Attention to equipment quality assurance and calibration is an important part of good laboratory practice. The minimum requirements are as follows: *1*) maintenance of a log of calibration results, *2*) documentation of repairs or other alterations that return the equipment to acceptable operation, *3*) recording of dates of computer software and hardware updates or changes, and *4*) recording the dates equipment is changed or relocated (e.g., industrial surveys). Calibration verifications and quality control procedures must be repeated after any such changes before further testing begins. Key aspects of

equipment quality assurance are summarized in Table 3.

A calibration procedure determines the relationship between flow or volume transducer signals measured by the sensor and the actual flow or volume. In contrast, a calibration verification is the procedure used to validate that the device is within calibration limits (i.e., ±3% [accuracy tolerance, ±2.5% for spirometers plus ±0.5% for calibration syringes]). Spirometry systems must include a calibration verification option using room air at ambient conditions. If a device fails its calibration verification (Table 4), then a new calibration procedure or equipment maintenance is required. Manufacturers must provide an alert if the new calibration factor either varies by more than ±2 SDs from the mean calibration factor or changes by more than 6% from the previous calibration factor, because this may indicate that the spirometer requires cleaning, maintenance, and/or repair. Calibration verifications must be undertaken daily, or more frequently if specified by the manufacturer. Precalibrated spirometers cannot be recalibrated by the operator but must still undergo a calibration verification. Manufacturers must specify the action to be taken if a precalibrated device fails the calibration verification. Spirometry software must include the ability to generate a report of calibrations that includes the results of all verifications, the number of failed calibration verifications in each session, and the changes in calibration factors. A warning should be issued if the calibration verification error differs from the historical mean calibration verification error by more than ±2 SDs (37, 39, 45, 46).

The spirometry system must determine the zero-flow level with the spirometer blocked before calibration, calibration verifications, and patient tests. If variable flow is detected during the zero-flow setting procedure or if the zero level has changed significantly, the zero-flow setting procedure must be repeated.

A 3-L syringe used to both recalibrate and verify the volume calibration of spirometers must have an accuracy of ±0.015 L or ±0.5% of the full scale, and the manufacturer must provide recommendations concerning appropriate intervals between checks of the syringe accuracy. The syringe must be kept at room temperature. Holding the syringe body to steady the syringe during a calibration verification can raise its temperature and contribute to measurement error. Operators should be aware that a syringe with an adjustable or variable stop may be out of calibration if the stop is reset or accidentally moved. 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 (47). A dropped or damaged syringe should be considered out of calibration until it is checked.

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). If an in-line filter is used in spirometry testing, then it must also be used during recalibrations and verifications. The measured volume at each flow must meet the accuracy requirement of ±3% for both inspiration and expiration (or for expiration only for volume-based spirometers). For devices using disposable flow sensors, a new sensor from the supply used for patient tests must be tested each day.

The *ATS Pulmonary Function Laboratory Management and Procedure Manual* (37) includes the option for a biological control: a healthy, nonsmoking individual capable of performing very repeatable spirometry. A biological control is not a substitute for the use of a calibration syringe. However, operators are encouraged to know their own usual $FEV_1$ and FVC, which allows them to conduct a quick, rough check if they suspect a problem. In some jurisdictions, including a biological control in quality control reporting may constitute a breach of employee privacy protection.

## Operator Details

As Ruppel and Enright observed, "There are 3 key elements to obtain high quality pulmonary function data: accurate and precise instrumentation, a patient/subject capable of performing acceptable and repeatable measurements, and a motivated technologist to elicit maximum performance from the patient. In the realm of standardization, the technologist has received the least attention" (48). The importance of the operator was also a key message derived from the patient experience survey.

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 (14, 15, 49–51), but short-term follow-up and supplementary training are important to maintain quality (52, 53). Operator training and attainment and maintenance of competency must be integrated in any spirometry testing service (54).

## Patient Details

The patient's age, height, and weight (wearing indoor clothes and without shoes) 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 (55) and weight to the nearest 0.5 kg must be recorded; these may also be expressed in inches and pounds on reports in jurisdictions still using those measures. Body mass index should be calculated as $kg/m^2$. 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) (56) or arm span (57) (*see* Section E6), 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.

Birth sex and ethnicity should be included in the patient information on the spirometry request. Otherwise, the operator will ask the patient to provide this information. When requesting birth sex data, patients should be given the opportunity to provide their gender identity as well and should be informed that although their gender identity is respected, it is birth sex and not gender that is the

**Table 3.** 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 (Table 4) 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 ⩾6% or varies by more than ±2 SD from the mean, inspect and, if necessary, clean the spirometer according to the manufacturer's instructions; check for errors (Table 4) 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 ±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

determinant of predicted lung size. Inaccurate entry of birth sex may lead to incorrect diagnosis and treatment. Similarly, patients should be informed of the need for reporting ethnicity (58). Ethnicity categories for the Global Lung Function Initiative (GLI) reference values (59) are white (i.e., European ancestry), African American, Northeast Asian, Southeast Asian, and other/mixed (Section E7). If birth sex and/or ethnicity data are not disclosed, the operator notes must alert the interpreter of this omission and state what default values were used for calculating predicted values.

### Patient Preparation

Patients should avoid the activities listed in Table 5 before testing, 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.

Patients should be as relaxed as possible before and during the tests. Patients should be asked to loosen tight-fitting clothing. Well-fitting dentures are usually left in place. A 2001 study found that spirometry results are generally better with dentures in place (60), but a larger 2018 study found that FVC was an average of 0.080 L higher when dentures were removed (61).

The decision to withhold long- and short-acting bronchodilators before testing is a clinical one determined by the referring healthcare professional. If the study is performed to diagnose an underlying lung condition, then withholding bronchodilators before testing is useful (*see* Bronchodilator Responsiveness Testing). For studies to determine a response to an existing therapeutic regimen, bronchodilator medications are generally not withheld.

Instructions on withholding medications should be given to the patient at the time of making the appointment. The operator must record the type and dosage of any inspired, oral, or injected medication that may alter lung function and when the drugs were last administered. The operator should record observed signs or symptoms such as cough, wheeze, dyspnea, or cyanosis.

**Table 4.** Potential Reasons for Calibration Verification Failure

- A slight change in spirometer function that requires a subsequent recalibration procedure to adjust the calibration factor
- A leak in the connection of the spirometer to the calibration syringe
- Air flow through the spirometer during the zero-flow setting procedure
- Failure to fully fill and empty the calibration syringe in one smooth action
- Calibration syringe malfunction (e.g., piston leak or displacement of the piston stop or syringe damaged by dropping)
- Spirometer blockage either by debris in the spirometer sensor or by the operator's hand while holding the spirometer in place
- Improper assembly of the sensor, mouthpiece, filter, and/or breathing tube
- Differences between room temperature and calibration syringe temperature
- Data entry errors in the ambient temperature and/or pressure

## $FEV_1$ and FVC Maneuver

### Test Procedure

For spirometers that measure inspiration and expiration, 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. Most of the variability in results obtained from spirometry relates to inadequate and variable inspiration to TLC, ending the expiration prematurely, and variable effort.

The operator must demonstrate the appropriate technique and follow the procedure described in Table 6. Once the zero-flow level has been determined, the patient should insert the mouthpiece and be instructed to breathe normally or easily. The operator checks that the patient has the proper posture, the noseclip is in place, and the lips are sealed around the mouthpiece. Patients unable to use a mouthpiece may be able to use a face mask (62). In some circumstances, such as patients with tracheostomy or nasal resection, noninvasive adjustments such as a sealing face mask, tubing connectors, or occlusion valves can be applied at the discretion of the operator and must be recorded in the operator notes.

***Maximal inspiration.*** Patients should be informed that maximal inflation is unnatural; they may not have achieved it before, and it may seem somewhat uncomfortable. Reductions in PEF and $FEV_1$ have been shown when inspiration is slow and/or there is a 4- to 6-second pause at TLC before beginning expiration (63, 64). It is therefore important that the preceding inspiration be rapid and any pause at full inspiration be minimal (⩽2 s).

**Table 5.** 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)

The operator should be in a position to view the patient and the display of the testing device, but the major sign that the subject has achieved full inflation will come from the patient. The patient's head and face should be observed while the command to "inspire as deeply as possible" (not just "take in a deep breath") is given. During the inspiration, the operator should coach the patient using phrases such as "more, more, more." Indicators of maximal inspiration include eyebrows raising or eyes widening, and sometimes the head begins to quiver. A patient who looks comfortable is not likely to be at full inflation.

***Maximal expiration.*** At full inflation, without hesitation, the patient should be prompted to "blast," not just "blow," the air from their lungs, and then he or she should be encouraged to fully expire. Continuous and enthusiastic coaching of the patient is required throughout the maneuver, using appropriate body language and phrases such as "keep going." The operator simultaneously observes the patient and the computer display during the test to help ensure maximal effort. The spirometry system must signal the operator when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds. Having an audio cue for end expiration permits the operator to observe the patient more closely. The patient survey indicated that many were concerned by being asked to keep blowing when they felt nothing more was coming out. If the patient is able to see a volume–time trace still moving as they blow and/or a numeric or analog display of flow in mL/s, this might help motivate them to keep blowing. Children may benefit from incentive displays. If the patient shows signs of syncope, the maneuver should be stopped. Reducing the effort partway through the maneuver (after 4 s) (65, 66) may give a higher expiratory volume in some patients and may prevent glottic closure and avoid syncope, but then it is no longer a true maximally forced expiration. Some patients with restrictive lung disease and young patients with high elastic recoil can empty their lungs quickly and may not be able to hold an expiratory plateau for 1 second. The operator needs to recognize the convex pattern of the flow–volume graph in such patients and distinguish it from an early termination of expiration (Figure E2).

***Maximal inspiration after forced expiration.*** Upon completing the forced expiration, the patient should remain on the mouthpiece, and the operator should again coach the patient to rapidly inspire to full inflation. This will provide a measure of forced inspiratory VC (FIVC). It is a maximal effort to return to TLC to complete the flow–volume loop. Comparison of the FIVC with the FVC will provide feedback to the operator on whether the patient began the forced expiration from full inflation (67). It is important that the inspiration to full inflation before and after the forced expiration be coached with equal vigor so that a valid comparison can be made.

With appropriate coaching, children as young as 2.5 years old with normal cognitive and neuromotor function are able to perform acceptable spirometry (8, 59). The operators who are involved in the pulmonary function testing of young children should be specifically trained and competent to work with this population. A child-friendly environment is important for successful testing. Encouragement, detailed but simple instructions, lack of intimidation, and visual feedback in the teaching are important in helping children to perform the maneuver (8, 68). Even if unsuccessful at the first session, children will learn to be less intimidated, and their performance may improve in subsequent sessions. Testing children in "adult" laboratories requires extra time and effort to cater to the specific needs of the younger patient (69). Other techniques such as raised volume rapid thoracic compression technique that are used for infants (70) are not included in this document.

For spirometers measuring expiration only, the procedure is modified as follows. The patient first inspires rapidly to maximal lung volume and then within 2 seconds inserts the mouthpiece, seals his or her lips around the mouthpiece, and initiates maximal expiration. Keeping the mouth open until the mouthpiece is in place can help minimize air loss before sealing the lips. The mouthpiece is removed at EOFE. Regarding expiration-only maneuvers, a study found that the use of noseclips did not affect group mean performance (71).

### Within-Maneuver Evaluation

The following criteria were developed as objective measures to determine whether a maximal effort was achieved and acceptable $FEV_1$ and/or FVC measurements were obtained. However, in some cases, maneuvers that do not meet all of the criteria may be the best that the patient is able to do on that occasion, and although the $FEV_1$ and/or FVC measurements are not technically acceptable, they may be clinically useful (i.e., "usable") (Table 7).

The start of forced expiration, for the purpose of timing, is determined by the back-extrapolation method (Figure 1) (1, 38). At the point of PEF on the volume–time graph, a tangent is drawn with a slope equal to PEF, and its intersection on the abscissa defines Time 0, which becomes the start for all timed measurements. The back-extrapolated volume (BEV) is the volume of gas that has already been expired from maximal lung volume to Time 0 and is included in the $FEV_1$ and FVC measurements. To ensure that the $FEV_1$ comes from a maximal effort, the BEV must be $<$5% of the FVC or 0.100 L, whichever is greater (72, 73). The 0.100-L tolerance is a reduction from the 0.150-L tolerance in the 2005 standards (1). The hesitation time, defined as the time from the point of maximal inspiration to Time 0, should be 2 seconds or less (Figure E13). $FEV_1$ and FVC measurements from a maneuver with BEV exceeding the limit are neither acceptable nor usable. A large BEV will usually result in an erroneously high $FEV_1$ (74). Patients with upper airway obstruction or neuromuscular disease are often unable to initiate a rapid increase in flow, and the BEV limit may be exceeded.

**Table 6.** 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 5, 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 ⩽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 $FEV_1$ 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 ⩽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 $FEV_1$ 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.

The operator must have the ability to override the BEV acceptability designation for such patients.

The volume–time graph must include 1 second before the start of forced expiration (Time 0) or begin before the point of maximum inspiration, whichever occurs first. The system should display the BEV value. Inspection of the flow–volume graph may be added as a measure of the satisfactory start of a test. PEF should be achieved with a sharp rise and occur close to Time 0 as measured by the rise time from 10% to 90% of peak flow (75), which should be ⩽150 ms but may be greater than this in a maneuver in a patient with upper airway obstruction.

***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 2):

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 an 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 >15 seconds will rarely change clinical decisions (1, 4). The 1994 ATS spirometry standards used "forced exhalation is of reasonable duration" as an indicator of EOFE and suggested that 12–15 seconds was sufficient (4). A study of adults (mean age, 67 yr) found that more than 95% of obstructed patients had an FET of <15 seconds and that >95% of normal subjects had an FET of <11 seconds (76). 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 (*see* below) of, the largest FVC observed before this maneuver in the current testing set. If the first maneuver of either the prebronchodilator testing set or the 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 <15 seconds that are within the repeatability tolerance of the maximum FVC in that set are judged to have met

**Table 7.** Summary of Acceptability, Usability, and Repeatability Criteria for $FEV_1$ and FVC

| Acceptability and Usability Criterion | Required for Acceptability | | Required for Usability | |
|---|---|---|---|---|
| | $FEV_1$ | FVC | $FEV_1$ | 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:<br>1. Expiratory plateau (≤0.025 L in the last 1 s of expiration)<br>2. Expiratory time ≥15 s<br>3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC† | No | Yes | No | No |
| 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 FIVC − FVC must be ≤0.100 L or 5% of FVC, whichever is greater‡ | Yes | Yes | No | No |

**Repeatability criteria** (applied to acceptable FVC and $FEV_1$ values)

Age >6 yr: The difference between the two largest FVC values must be ≤0.150 L, and the difference between the two largest $FEV_1$ 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 $FEV_1$ 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; $FEV_{0.75}$ = forced expiratory volume in the first 0.75 seconds; FIVC = forced inspiratory VC.

The grading system (Table 10) 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 $FEV_{0.75}$.

†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 when the patient inspires or comes off the mouthpiece before a plateau. For within-maneuver acceptability, the FVC must be greater 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.

‡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.

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 $FEV_1$ measurement may be obtained from a maneuver with early termination after 1 second. For children aged 6 years or younger, an acceptable $FEV_{0.75}$ (the forced expiratory volume in the first 0.75 s) may be obtained from a maneuver with early termination after 0.75 seconds.

Note that there is no requirement for a minimum FET. Studies have shown that patients with airflow obstruction and elderly patients may have difficulty meeting the 2005 ATS/ERS requirement of achieving a plateau (77–79), and the criterion results in the exclusion of too many patients while having minimal impact on predicted values (80). A large occupational health study in an older population (mean age, 63 yr) found that 53% of spirometry maneuvers failed to reach a plateau despite encouragement by trained operators and long FETs (72). However, in another study, 90% of patients with severe lung function impairment were able to meet the criteria (81). Other large adult population studies found that more than 95% of subjects who expired for longer than 6 seconds achieved a plateau (82, 83). A large clinical trial using well-trained, supervised operators found that 94% of patients with COPD were able to meet the 1994 ATS spirometry standards plateau criteria (4, 84).

The 2005 ATS/ERS requirement of a minimum FET (1) resulted in some valid maneuvers being classified as inadequate (77, 78, 85). In a study of 1,631 healthy children aged 10–18 years, only 18% met the 2005 minimum FET in maneuvers that were visually judged to be acceptable (73). However, because the requirement for a minimum FET has been eliminated, increased vigilance by the operator and the interpreter is required in the assessment of whether expiration was complete or there was early termination.

If the volume of the maximal inspiration (i.e., FIVC) after EOFE is greater than FVC, then the patient did not start the maneuver from TLC. $FEV_1$ and FVC measurements from a maneuver with FIVC − FVC > 0.100 L or 5% of FVC, whichever is greater, are not acceptable.

A cough during the first second of the maneuver can affect the measured $FEV_1$ value, and the $FEV_1$ from such a maneuver is neither acceptable nor usable. However, the FVC may be acceptable.

Glottic closure or early termination, such as inspiration or coming off the mouthpiece, renders FVC unacceptable and, if it occurs in the first 1 second, renders $FEV_1$ unacceptable and unusable. A similar

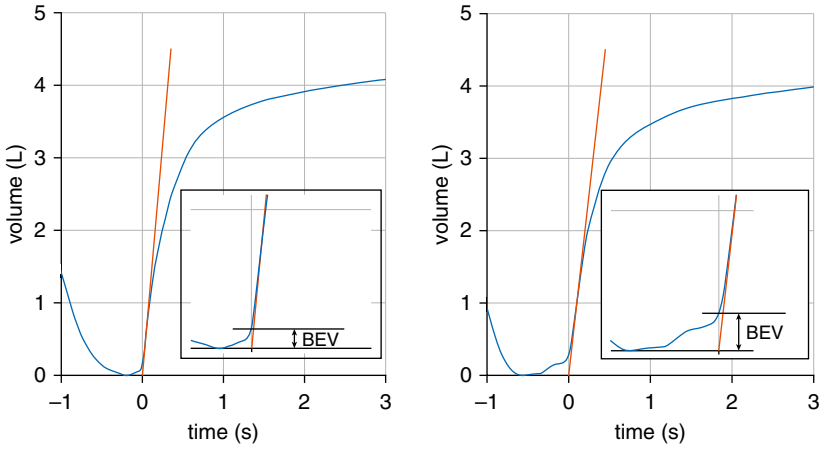


**Figure 1.** Back-extrapolated volume (BEV). Time 0 is found by drawing a line with a slope equal to peak flow through the point of peak flow (red line) on the volume–time curve and setting Time 0 to the point where this line intersects the time axis. The BEV is equal to the volume of gas exhaled before Time 0 (inset), which, in these two examples from the same patient, is 0.136 L for the left panel (acceptable) and 0.248 L for the right panel (unacceptable). For this patient, the BEV limit is 5% FVC = 0.225 L.

termination in the first 0.75 seconds renders $FEV_{0.75}$ unacceptable and unusable.

There must be no leak at the mouth (4). Patients with difficulty making a seal around the mouthpiece may require a flange-type mouthpiece or assistance from the operator to guarantee an adequate seal.

Obstruction of the mouthpiece (e.g., by the tongue being placed in front of the mouthpiece, by teeth in front of the mouthpiece, or by distortion from biting) may affect the performance of either the device or the patient. Errors also occur because of obstruction of a handheld spirometer by improper hand placement.

Maneuvers conducted with an erroneous zero-flow level will either under- or overestimate $FEV_1$ and FVC. Figure E13 shows the effects of a faulty zero-flow set procedure that renders both $FEV_1$ and FVC neither acceptable nor usable.

***Operator feedback.*** The spirometry system software must provide explicit feedback to the operator indicating $FEV_1$ and FVC acceptability at the completion of each maneuver. Sample warning messages and suggested corrections are provided in Section E8. 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 $FEV_1$ and/or FVC that are acceptable or usable must be retained because, for some patients, their best performance may yield only usable data that does not meet acceptability criteria. Examples of acceptable and unacceptable volume–time curves and corresponding flow–volume curves are provided in Figures E1–E12.

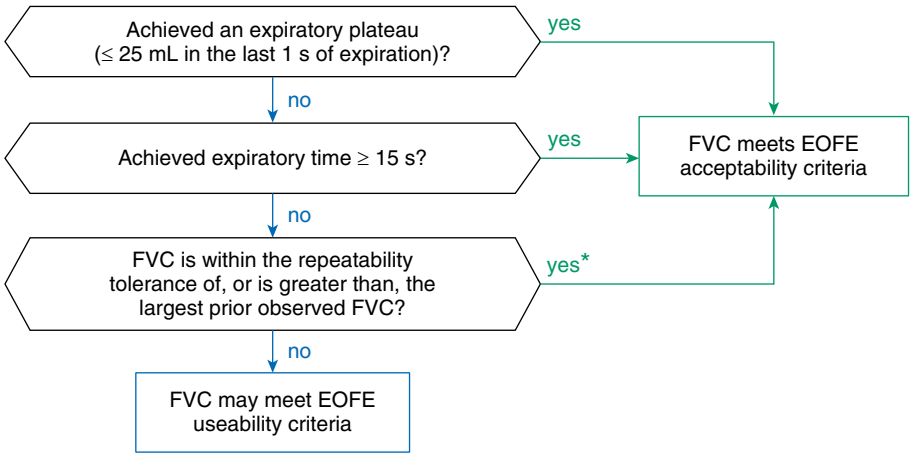


**Figure 2.** Flowchart outlining the end of forced expiration (EOFE) acceptability criteria for FVC. *If there are no prior observed FVC values in the current pre- or post-bronchodilator testing set, then the FVC provisionally meets EOFE acceptability criteria.

### Between-Maneuver Evaluation

The goal of each prebronchodilator testing set and post-bronchodilator testing set is to achieve a minimum of three acceptable $FEV_1$ and three acceptable FVC measurements. Note that acceptable $FEV_1$ and acceptable FVC measurements are not necessarily from the same maneuver. The operator must ensure that sufficient time is allowed between maneuvers for the patient to sufficiently recover and agree to perform another maximal maneuver. FVC repeatability is achieved when the difference between the largest and the next largest FVC is ⩽0.150 L for patients older than 6 years of age (86) and ⩽0.100 L or 10% of largest FVC, whichever is greater, for those aged 6 years or younger (8, 87). For $FEV_1$ repeatability, the difference between the largest and the next largest $FEV_1$ is ⩽0.150 L for those older than 6 years of age and ⩽0.100 L or 10% of the largest $FEV_1$, 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 3).

Achieving repeatable results is the best indicator that the patient performed the maximal $FEV_1$ 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), guides the confidence level in the interpretation of the results. The repeatability criteria are used to determine when more maneuvers are needed. In many cases, patients can and will achieve closer repeatability than these criteria. Studies have found that most adults are able to achieve FVC and $FEV_1$ repeatability to within 0.150 L (82, 88) and that children are able to achieve repeatability within 0.150 or 0.100 L (89).

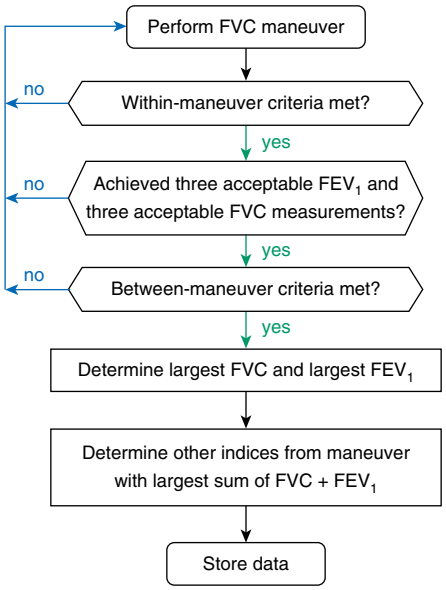


**Figure 3.** Flowchart outlining application of acceptability and repeatability criteria.

### Maximum Number of Maneuvers

Although there may be some circumstances in which more than eight consecutive FVC maneuvers may be needed, eight is generally a practical upper limit for most adults (90, 91). After several forced expiratory maneuvers, fatigue can begin to take its toll on patients, and additional maneuvers would be of little added value. In rare circumstances, patients may show a progressive reduction in $FEV_1$ or FVC with each subsequent maneuver. If the $FEV_1$ from an acceptable test drops below 80% of the start value, the test procedure should be terminated in the interest of patient safety. When testing children, more than eight attempts may be required because each attempt may not be a full maneuver. Children may benefit from practicing the different phases of the maneuver before attempting a full maneuver. Operators should be aware of the child's enthusiasm and effort to avoid exhausting or discouraging the child from future testing.

## 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 (92). Bronchodilator responsiveness testing is a determination of the degree of improvement of airflow in response to bronchodilator administration as measured by changes in $FEV_1$ and FVC. It is commonly undertaken as part of spirometry testing. The choice of bronchodilator, dose, and mode of delivery is a clinical decision depending on what the referring clinician wishes to learn from the test.

If the aim of the test is to determine whether the patient's spirometric lung function can be improved with therapy in addition to their regular treatment, then the patient may continue with his or her regular medication before the test. If the test is used for diagnosis or to determine whether there is any change in spirometric lung function in response to bronchodilators, then the clinician ordering spirometry will instruct the patient to withhold bronchodilators before baseline testing. Table 8 lists suggested withholding times for various bronchodilators. The withholding times are based on studies of the lasting bronchodilator effects of the various agents (93, 94). Inhaled corticosteroids and leukotriene modifiers need not be withheld. It is important to notify and remind the patient about withholding medications before the test and confirm withholding at the time of the test (95).

Because normal baseline spirometry does not rule out a bronchodilator response, all initial spirometry done for diagnostic reasons should be performed before and after bronchodilator administration. Thereafter the clinician may choose to perform spirometry without bronchodilator responsiveness testing, but it is important to consider baseline variability in lung function when making this decision. Monitoring lung function by serial spirometry, especially in patients with obstructive lung disease, may be more useful by following post-bronchodilator values (96).

### Test Procedure

The patient first performs prebronchodilator spirometry to achieve three acceptable $FEV_1$ 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 (Section E9). Three or more additional post-bronchodilator acceptable $FEV_1$ 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.

It is not uncommon for a post-bronchodilator maneuver to be erroneously coded as prebronchodilator, or the converse. The spirometry system must permit the operator to change the designation of the maneuver from pre- to post-bronchodilator, and vice versa, so that a good maneuver is not lost and the patient is not required to perform an additional unwarranted maneuver. When the first post-bronchodilator maneuver is initiated by the operator, the system must display the time elapsed since the last prebronchodilator maneuver. If the elapsed time is less than the wait time for the bronchodilator effect, then the system must provide a warning message to the operator.

## Reported Values

The following measurements are reported separately for the sets of prebronchodilator and post-bronchodilator maneuvers (Table 9). The largest FVC and the largest $FEV_1$ observed from all of the acceptable values are reported (or largest usable values if none are acceptable). Their ratio is used for $FEV_1$/FVC, even though the largest FVC and the largest $FEV_1$ may not necessarily come from the same maneuver. If a bronchodilator is administered, both the percentage change and the absolute change in $FEV_1$ and FVC compared with prebronchodilator values are reported. Recent studies showed that reporting the change in $FEV_1$ as a percentage of the predicted $FEV_1$ or as *z*-scores avoids sex and height bias in assessing bronchodilator responsiveness (97, 98).

FIVC is the largest inspiratory volume immediately after forced expiration from all of the maneuvers. PEF is the highest flow achieved from a maximum forced expiratory maneuver started without hesitation from a position of maximal lung inflation. The largest value from maneuvers meeting the acceptability criteria for $FEV_1$ in Table 7 is reported.

FET is the time in seconds measured from Time 0 to the end of the expiratory plateau or the beginning of inspiration after maximal forced expiration, or the time that the patient comes off the mouthpiece,

**Table 8.** 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 $\beta_2$-agonist; LAMA = long-acting muscarinic antagonist; SABA = short-acting $\beta_2$-agonist; SAMA = short-acting muscarinic antagonist.
*Note*: Withholding times for post-bronchodilator testing are shorter than those for methacholine challenge testing (147) 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.

whichever is shortest. The FET does not include any period of zero flow at the end of expiration. The FET from the maneuver with the largest FVC is reported. For patients with airflow obstruction, the FVC may depend on FET. The interpreter must be aware that an apparent change in FVC after bronchodilator administration may be due to a change in FET.

$FEV_t$ is the maximal volume expired by Time *t* seconds from Time 0 of a forced expiratory maneuver. Children aged 6 years or younger have relatively large airways compared with their lung volume and may complete expiration in <1 second. Therefore, $FEV_{0.75}$ and $FEV_{0.5}$ have been used. In children aged 6 years or younger, $FEV_{0.75}$ was found to provide information similar to that of $FEV_1$ (99, 100). The ATS/ERS statement on pulmonary function testing in preschool children states that $FEV_{0.75}$ and $FEV_{0.5}$ should be reported (8). However, because GLI reference values for $FEV_{0.75}$ (but not for $FEV_{0.5}$) are available for ages 3–7 years (59), $FEV_{0.75}$ should be reported for children aged 6 years or younger, and if FET is >1 second, then $FEV_1$ should also be reported.

The mean forced expiratory flow, midexpiratory phase ($FEF_{25-75}$), may be reported from the maneuver with the largest sum of $FEV_1$ and FVC. It should be noted that $FEF_{25-75}$ is highly dependent on the validity of the FVC measurement and the degree of expiratory effort. A volume adjustment may be required when comparing pre- and post-bronchodilator $FEF_{25-75}$ values (101).

**Table 9.** Measured Variables (Reported Separately for Pre- and Post-bronchodilator Tests)

| Variable | Units |
|---|---|
| FVC | Liters |
| $FEV_1$ | Liters |
| $FEV_1$/FVC | Decimal fraction to two decimal places |
| PEF | Liters per second |
| FET | Seconds |
| FIVC | Liters |
| For children ≤6 yr | |
| $FEV_{0.75}$ | Liters |
| $FEV_{0.75}$/FVC | Decimal fraction to two decimal places |

*Definition of abbreviations*: FET = forced expiratory time; $FEV_{0.75}$ = forced expiratory volume in the first 0.75 seconds; FIVC = forced inspiratory VC; PEF = peak expiratory flow.
Volumes in liters and PEF in L/s are reported to two decimal places at BTPS (body temperature, ambient barometric pressure, and saturated with water vapor). Spirometry systems must be capable of measuring these variables and reporting them as recommended in the American Thoracic Society standardized format (114). Although $FEV_1$, FVC, and $FEV_1$/FVC are obligatory, the facility manager must have the ability to configure the report to include the other optional variables, such as $FEV_6$, $FEV_1/FEV_6$, $FEV_{0.5}$, and mean forced expiratory flow, midexpiratory phase (forced expiratory flow between 25% and 75% of the FVC).

### Other Derived Indices

$FEV_1/FEV_6$ has been shown to be useful in the diagnosis of airflow obstruction in adults (102, 103). Recording $FEV_6$ has the advantages of being more reproducible than FVC, being less physically demanding for patients, reducing the risk of syncope, and providing a more explicit EOFE (104–107). Appropriate reference values for $FEV_6$ must be used (108–111). The ratio of FEF at 50% VC to forced inspiratory flow at 50% VC ($FEF_{50}/FIF_{50}$) is sometimes used as an indicator of upper airway obstruction (112, 113). A table of all of the measurements required to be available and stored is provided in the online supplement (Section E10).

The ATS standardized report form (114) should be the default report form for spirometry systems. The default set of reference values for all ages should be the GLI reference equations (59), 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 E10). The system should also have the capability to export data to electronic medical records, both as .pdf file copies of the printed report and as discrete data, using the Clinical Document Architecture Release 2 standard of HL7 International (115) 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.

The date and time for each maneuver must be recorded. Diurnal variations of 3% in $FEV_1$ and 6% in PEF have been reported (116), with lower values noted in patients with COPD in the afternoon compared with the morning (117). In addition, the time data are useful for verifying pre- and post-bronchodilator maneuvers.

Operator comments are a key part of the report. The system must permit the operator to enter comments from a

**Table 10.** Grading System for $FEV_1$ 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 $FEV_1$ 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 114.
*Or 10% of the highest value, whichever is greater; applies for age 6 years or younger only.

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 given in Section E11.

## 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, 86, 114, 118).

The grading system that is recommended by the ATS for spirometry reporting (114), which is a modified version of the system developed by Hankinson and colleagues (80) and expanded to include young children, should be used (Table 10). Grade "U" was added to denote "usable" values. $FEV_1$ 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 grade 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 the grade refers to the consistency of their blows.

## VC and Inspiratory Capacity Maneuver

The VC is the volume change between TLC and residual volume (RV). The slow VC can be derived in two ways. The expiratory VC (EVC) is the volume of gas slowly expired from TLC to RV. The inspiratory VC (IVC) is the volume of gas slowly inspired from RV to TLC (Figure 4). These maneuvers are unforced, except at the point of reaching RV or TLC, respectively, when extra effort is required (119).

Inspiratory capacity (IC) is the volume change recorded at the mouth when taking a slow full inspiration with no hesitation, inspiring from a position of passive end-tidal expiration (i.e., FRC) to a position of maximum inspiration (i.e., TLC). IC is an indirect estimate of the degree of lung hyperinflation at rest and is useful to assess changes in FRC with pharmacological interventions and physical exercise (120–123).

### Equipment

For measurements of VC and IC, the spirometer must comply with the requirements for FVC maneuvers above. VC can be measured using conventional spirometers or equipment used to measure static lung volumes and their subdivisions (124). Both inspiratory and expiratory maneuvers must be included in the display of the VC maneuver. Regardless of whether the inspiratory or expiratory maneuver is used for deriving measurements, a display of the entire recorded VC maneuver must be provided to determine whether the patient obtained a plateau in the expiratory effort.

### Test Procedure

For a slow VC, a maximum of eight maneuvers is a practical upper limit. It is preferable that VC maneuvers be performed before FVC maneuvers because of the potential for muscular fatigue and volume history effects, whereby, after maximal inspiratory efforts, some patients with severe airway obstruction return to a falsely

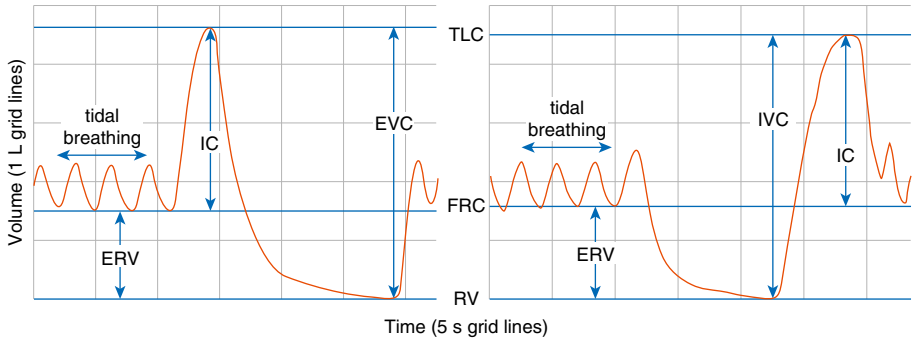


**Figure 4.** Measurement of VC and IC. VC may be measured either as EVC (left panel) or IVC (right panel). In these examples, divisions on the volume axis are 1 L, and those on the time axis are 5 seconds. ERV = expiratory reserve volume; EVC = expiratory VC; IC = inspiratory capacity; IVC = inspiratory VC; RV = residual volume.

high level of FRC or RV as a result of gas trapping or stress relaxation (4). The VC maneuver may measure either IVC or EVC (Figure 4). Important differences between IVC and EVC maneuvers may be observed in patients with airway obstruction (125–127).

Patients should be relaxed, seated erect with a noseclip in place, and asked to breathe normally until the end-expiratory lung volume is stable. Stability is defined as having at least three tidal breaths with end-expiratory lung volume within 15% of the $V_T$. If this is not achieved within 10 breaths, the VC part of the maneuver may begin, but the IC will not be reliable. The patient is then urged either *1*) to take a deep breath to TLC with no hesitation and expire to RV or *2*) to breathe all the way out to RV and then take a deep breath in to TLC, and then breathe normally (Figure 4).

The maneuver is not forced but is performed in a relaxed manner, except near end inspiration and end expiration. The operator should encourage the patient to reach maximal inspiratory and expiratory volumes with a relatively constant flow. In healthy patients, adequate maximal inspiratory and expiratory levels are achieved within 5–6 seconds. Patients with airway obstruction will take longer, but expiration should be terminated after 15 seconds. The expiration should not be excessively slow, because this can lead to underestimation of VC. Operators should observe the patient carefully to ensure that his or her lips are sealed around the mouthpiece, nothing obstructs the mouthpiece, the noseclip is in place with no leaks, and TLC and RV are reached. The system must provide both a visual and an audible signal (single beep) when a stable end-expiratory tidal lung volume is detected or there have been 10 tidal breaths and, for expiration to RV in either IVC or EVC maneuvers, a double beep when a plateau is reached ($<$0.025 L in the last second) or the expiration time reaches 15 seconds.

For within-maneuver evaluation, there must be no leak at the mouth or nose and no obstruction of the mouthpiece. The IC may be underestimated if the inspiratory maneuver is too slow because of poor effort or hesitation or if there is premature closure of the glottis.

For between-maneuver evaluation, as with forced maneuvers, a minimum of three acceptable VC maneuvers must be obtained. If the difference in VC between the largest and next largest maneuver is $>$0.150 L or 10% VC, whichever is smaller, for patients older than 6 years of age or $>$0.100 L or 10% VC, whichever is smaller, for those aged 6 years or younger, then additional trials should be undertaken. Meeting repeatability criteria may require performing up to eight maneuvers, with sufficient rest time between the maneuvers so that the operator and patient agree that the next maneuver may begin. Large variability in this test is often due to incomplete inspiration. For VC, the largest value from at least three acceptable maneuvers should be reported. For maneuvers in which stable end-expiratory tidal lung volume was not attained, IC is not reported. For IC, the average value from the acceptable maneuvers should be reported.

## Further Studies

An analysis of BEV measures from both children and adults is needed to develop evidence-based criteria for acceptable BEV limits. An analysis of FETs in patients with airflow obstruction is needed to determine better criteria for maneuver acceptability and the impact of shorter FETs in these patients on their diagnosis. Research is needed to validate the EOFE plateau criterion ($\leq$0.025 L in 1 s), which is based on expert opinion dating back to 1979 (2). Other unknowns include the optimal resting time between maneuvers and the effect of mouthpiece shape (round, oval, and flared). Updated standards are required for unattended home monitoring spirometry (128–130) and peak flow monitoring. A grading system for the slow VC needs to be developed and evaluated. Studies have shown that ongoing supervised training using a telemedicine system is effective and valid for assessing and monitoring the quality of the spirometry tests performed in primary health centers in a public health system (131, 132).

### Other Potential Analyses

Although $FEV_1$ and FVC are the primary variables measured in spirometry, there is far more information contained in the flow and volume data. Continuing research on innovative analyses that may improve diagnoses or lead to earlier diagnosis in at-risk persons is important, and new methods of measuring volume and flow are strongly encouraged.

Measures of curve shape using flow and volume signal analyses have good agreement with expert impression of expiratory flow–volume curve concavity, which is useful in assessing asthma and cystic fibrosis in children (133). The slope ratio may be useful in mild COPD (134). The calculation of Time 0 may be improved by breakpoint methods using a recursive, segmented linear regression technique (135).

More advanced analyses of the flow and volume data have been proposed to assist in the automation of spirometry quality assessment (136–138) and to automatically detect errors in early termination, cough, extra breaths, and variable flow (139). A system developed using machine learning techniques demonstrated a credible potential to differentiate acceptable maneuvers from ones with poor quality, with performance rates near the level of experts (140).

A study found that an isolated reduction of the $FEV_3$/FVC ratio is an

indicator of mild lung injury (141), and reductions in $FEV_1/FEV_6$ (142) or $FEV_3/FEV_6$ (143) may have higher sensitivity than $FEV_1$/FVC for detecting early airflow limitation. Lower limits of normal have been derived for $FEV_1/FEV_6$, $FEV_3/FEV_6$, and $FEV_3$/FVC (109). Estimating FVC using data from the first 2–3 seconds of expiration might potentially either assist in determining whether EOFE was attained or provide a surrogate for FVC when EOFE is not attained (144, 145). Imaging technology has the potential to monitor spirometry without a direct connection to the patient (146), permitting testing of patients unable or unwilling to use a mouthpiece. ■

This official technical statement was prepared by a joint ATS/ERS task force.

**Members of the task force are as follows:**

Brian L. Graham, Ph.D.[1] (*Chair*)
Irene Steenbruggen, R.P.F.T.[2] (*Co-Chair*)
Igor Z. Barjaktarevic, Ph.D., M.D.[3]
Brendan G. Cooper, Ph.D.[4,5]
Graham L. Hall, Ph.D.[6,7]
Teal S. Hallstrand, M.D., M.P.H.[8]
David A. Kaminsky, M.D.[9]
Kevin McCarthy, R.P.F.T.[10]
Meredith C. McCormack, M.D., M.H.S.[11]
Martin R. Miller, M.D.[12]
Cristine E. Oropez, M.D.[13]
Margaret Rosenfeld, M.D., M.P.H.[14]
Sanja Stanojevic, Ph.D.[15]
Maureen P. Swanney, Ph.D.[16]
Bruce R. Thompson, Ph.D.[17]

[1]Respiratory Research Centre, Division of Respirology, Critical Care and Sleep Medicine, University of Saskatchewan, Saskatoon, Saskatchewan, Canada; [2]Department of Pulmonology, Isala Hospital, Zwolle, the Netherlands; [3]Pulmonary and Critical Care Medicine, University of California, Los Angeles, Los Angeles, California; [4]Lung Function & Sleep Department, Queen Elizabeth Hospital, Birmingham, United Kingdom; [5]University Hospitals Birmingham NHS Foundation Trust, Birmingham, United Kingdom; [6]Children's Lung Health, Telethon Kids Institute, Perth Children's Hospital, Perth, Australia; [7]School of Physiotherapy and Exercise Science, Faculty of Health Science, Curtin University, Bentley, Perth, Australia; [8]Division of Pulmonary, Critical Care and Sleep Medicine, Department of Medicine, University of Washington, Seattle, Washington; [9]Pulmonary Disease and Critical Care Medicine, University of Vermont Larner College of Medicine, Burlington, Vermont; [10]ERT Inc., Matthews, North Carolina; [11]Pulmonary Function Laboratory, Pulmonary and Critical Care Medicine, Johns Hopkins University, Baltimore, Maryland; [12]Institute of Applied Health Research, University of Birmingham, Birmingham, United Kingdom; [13]Pulmonary Function and Exercise Physiology Laboratory, Department of Medicine, University of Arizona, Tucson, Arizona; [14]Division of Pulmonary and Sleep Medicine, Department of Pediatrics, University of Washington School of Medicine, Seattle, Washington; [15]Translational Medicine, The Hospital for Sick Children, Toronto, Ontario, Canada; [16]Department of Respiratory Medicine, Canterbury District Health Board, Christchurch, New Zealand; and [17]Physiology Service, Department of Respiratory Medicine, The Alfred Hospital and School of Health Sciences, Swinburne University of Technology, Melbourne, Australia

**Author Disclosures:** I.Z.B. served on an advisory committee for GlaxoSmithKline; served as a consultant for AstraZeneca, Boehringer Ingelheim, CSL Behring, Fisher & Paykel Healthcare, GE Healthcare, Grifols, Mylan/Theravance, and Verona Pharma; and received research support from AMGEN, GE Healthcare, and Prolung. B.G.C. received research support from ndd Medical Technologies and MedChip. G.L.H. served on an advisory committee for and received research support from Vertex. D.A.K. served as a speaker for MGC Diagnostics; served as a consultant for Spiration; and served on a data and safety monitoring board for Acorda. K.M. served as a speaker for Medical Graphics Corporation and Genentech; and served on an advisory committee for Genentech. M.C.M. received royalties from UpToDate; and served on an advisory committee for GlaxoSmithKline. B.R.T. served as a consultant for Boehringer Ingelheim, GlaxoSmithKline, and ndd Medical Technologies; served on an advisory committee for Bayer; received royalties from UpToDate; and served on a data and safety monitoring board for Faron and Ferring Labs. B.L.G., I.S., T.S.H., M.R.M., C.E.O., M.R., S.S., and M.P.S. reported no relevant commercial relationships.

**Acknowledgment:** The task force is grateful for the support of the European Lung Foundation in the design, implementation, and analysis of the spirometry patient survey.

## References

1. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, *et al*.; ATS/ERS Task Force. Standardisation of spirometry. *Eur Respir J* 2005;26:319–338.
2. American Thoracic Society. ATS statement: snowbird workshop on standardization of spirometry. *Am Rev Respir Dis* 1979;119:831–838.
3. Statement of the American Thoracic Society. Standardization of spirometry: 1987 update. *Am Rev Respir Dis* 1987;136:1285–1298.
4. American Thoracic Society. Standardization of spirometry, 1994 update. *Am J Respir Crit Care Med* 1995;152:1107–1136.
5. Quanjer PH. Standardized lung function testing: report working party standardization of lung function tests. *Bull Eur Physiopathol Respir* 1983;19(Suppl 5):1–95.
6. Quanjer PH, Tammeling GJ, Cotes JE, Pedersen OF, Peslin R, Yernault JC. Lung volumes and forced ventilatory flows. *Eur Respir J* 1993; 6(Suppl 16):5–40.
7. Redlich CA, Tarlo SM, Hankinson JL, Townsend MC, Eschenbacher WL, Von Essen SG, *et al*.; American Thoracic Society Committee on Spirometry in the Occupational Setting. Official American Thoracic Society technical standards: spirometry in the occupational setting. *Am J Respir Crit Care Med* 2014;189:983–993.
8. Beydon N, Davis SD, Lombardi E, Allen JL, Arets HG, Aurora P, *et al*.; American Thoracic Society/European Respiratory Society Working Group on Infant and Young Children Pulmonary Function Testing. An official American Thoracic Society/European Respiratory Society statement: pulmonary function testing in preschool children. *Am J Respir Crit Care Med* 2007;175:1304–1345.
9. Graham BL. Pulmonary function standards: a work in progress. *Respir Care* 2012;57:1199–1200.
10. Miller MR, Crapo R, Hankinson J, Brusasco V, Burgos F, Casaburi R, *et al*.; ATS/ERS Task Force. General considerations for lung function testing. *Eur Respir J* 2005;26:153–161.
11. Hegewald MJ, Gallo HM, Wilson EL. Accuracy and quality of spirometry in primary care offices. *Ann Am Thorac Soc* 2016;13:2119–2124.
12. Schermer TRJ, Verweij EHA, Cretier R, Pellegrino A, Crockett AJ, Poels PJ. Accuracy and precision of desktop spirometers in general practices. *Respiration* 2012;83:344–352.
13. Bambra G, Jalota L, Kapoor C, Mills PK, Vempilly JJ, Jain VV. Office spirometry correlates with laboratory spirometry in patients with symptomatic asthma and COPD. *Clin Respir J* 2017;11:805–811.
14. Licskai CJ, Sands TW, Paolatto L, Nicoletti I, Ferrone M. Spirometry in primary care: an analysis of spirometery test quality in a regional primary care asthma program. *Can Respir J* 2012;19: 249–254.
15. Epton MJ, Stanton JD, McGeoch GR, Shand BI, Swanney MP. The development of a community-based spirometry service in the Canterbury region of New Zealand: observations on new service delivery. *NPJ Prim Care Respir Med* 2015;25:15003.
16. Cooper BG. An update on contraindications for lung function testing. *Thorax* 2011;66:714–723.

17. Coates AL, Graham BL, McFadden RG, McParland C, Moosa D, Provencher S, *et al*.; Canadian Thoracic Society. Spirometry in primary care. *Can Respir J* 2013;20:13–21.
18. Vieira GM, Oliveira HB, de Andrade DT, Bottaro M, Ritch R. Intraocular pressure variation during weight lifting. *Arch Ophthalmol* 2006;124: 1251–1254.
19. Tiller NB, Simpson AJ. Effect of spirometry on intra-thoracic pressures. *BMC Res Notes* 2018;11:110.
20. Boerrigter BG, Bogaard HJ, Vonk-Noordegraaf A. Spirometry in chronic obstructive pulmonary disease: a hemodynamic roller coaster? *Am J Respir Crit Care Med* 2012;186:e6–e7.
21. Roberts C, Ward S, Walsted E, Hull JH. Safety of pulmonary function testing: data from 20 years. *Thorax* 2018;73:385–387.
22. García-Río F, Calle M, Burgos F, Casan P, Del Campo F, Galdiz JB, *et al*.; Spanish Society of Pulmonology and Thoracic Surgery (SEPAR). Spirometry. *Arch Bronconeumol* 2013;49:388–401.
23. Araújo CG, Vianna LC. How often does spirometry testing induce cardiac arrhythmias? *Prim Care Respir J* 2009;18:185–188.
24. Zagami D, Wilson J, Bodger A, Sriram KB. Respiratory function testing is safe in patients with abdominal aortic aneurysms. *Vasc Endovascular Surg* 2014;48:522–523.
25. Goodyear SJ, Yow H, Saedon M, Shakespeare J, Hill CE, Watson D, *et al*. Risk stratification by pre-operative cardiopulmonary exercise testing improves outcomes following elective abdominal aortic aneurysm surgery: a cohort study. *Perioper Med (Lond)* 2013;2:10.
26. Frost F, Peat R, McWean J, Shaw M, Field M, Nazareth D, *et al*. Pulmonary function testing is safe in patients with thoracic aortic aneurysms. *Eur Respir J* 2018;52:1800928.
27. Johns DP, Hartley MF, Burns G, Thompson BR. Variation in barometric pressure in Melbourne does not significantly affect the BTPS correction factor. *Respirology* 2004;9:406–408.
28. Lalloo UG, Becklake MR, Goldsmith CM. Effect of standing versus sitting position on spirometric indices in healthy subjects. *Respiration* 1991;58:122–125.
29. Gudmundsson G, Cerveny M, Shasby DM. Spirometric values in obese individuals: effects of body position. *Am J Respir Crit Care Med* 1997;156:998–999.
30. Swamy K, Isroff C, Mhanna MJ, Chouksey AK. Effect of sitting vs standing posture on spirometry in children. *Ann Allergy Asthma Immunol* 2016;117:94–96.
31. Pal AK, Tiwari S, Verma DK. Effect of recumbent body positions on dynamic lung function parameters in healthy young subjects. *J Clin Diagn Res* 2017;11:CC08–CC10.
32. Katz S, Arish N, Rokach A, Zaltzman Y, Marcus EL. The effect of body position on pulmonary function: a systematic review. *BMC Pulm Med* 2018;18:159.
33. Kendrick AH, Johns DP, Leeming JP. Infection control of lung function equipment: a practical approach. *Respir Med* 2003;97:1163–1179.
34. Rasam SA, Apte KK, Salvi SS. Infection control in the pulmonary function test laboratory. *Lung India* 2015;32:359–366.
35. Pittet D, Allegranzi B, Boyce J; World Health Organization World Alliance for Patient Safety First Global Patient Safety Challenge Core Group of Experts. The World Health Organization guidelines on hand hygiene in health care and their consensus recommendations. *Infect Control Hosp Epidemiol* 2009;30:611–622.
36. Saiman L, Siegel JD, LiPuma JJ, Brown RF, Bryson EA, Chambers MJ, *et al*.; Cystic Fibrous Foundation; Society for Healthcare Epidemiology of America. Infection prevention and control guideline for cystic fibrosis: 2013 update. *Infect Control Hosp Epidemiol* 2014; 35(Suppl 1):S1–S67.
37. Wanger J, Mottram C. ATS pulmonary function laboratory management and procedure manual, 3rd ed. New York: American Thoracic Society; 2016.
38. International Organization for Standardization. ISO 26782. Anaesthetic and respiratory equipment: spirometers intended for the measurement of time forced expired volumes in humans. Geneva, Switzerland: International Organization for Standardization; 2016.
39. McCormack MC, Shade D, Wise RA. Spirometer calibration checks: is 3.5% good enough? *Chest* 2007;131:1486–1493.
40. Lefebvre Q, Vandergoten T, Derom E, Marchandise E, Liistro G. Testing spirometers: are the standard curves of the American Thoracic Society sufficient? *Respir Care* 2014;59:1895–1904.
41. Miller MR, Lloyd J, Bright P. Recording flow in the first second of a maximal forced expiratory manoeuvre: influence of frequency content. *Eur Respir J* 2002;19:530–533.
42. Graham BL, Brusasco V, Burgos F, Cooper BG, Jensen R, Kendrick A, *et al*. 2017 ERS/ATS standards for single-breath carbon monoxide uptake in the lung. *Eur Respir J* 2017;49:1600016.
43. Miller MR, Sigsgaard T. Prevention of thermal and condensation errors in pneumotachographic recordings of the maximal forced expiratory manoeuvre. *Eur Respir J* 1994;7:198–201.
44. Johnson LR, Enright PL, Voelker HT, Tashkin DP. Volume spirometers need automated internal temperature sensors. *Am J Respir Crit Care Med* 1994;150:1575–1580.
45. Haynes JM, Ruppel GL. Should spirometer quality control be treated like other laboratory devices? *ERJ Open Res* 2019;5:00249-2018.
46. Westgard JO, Groth T, Aronsson T, Falk H, de Verdier CH. Performance characteristics of rules for internal quality control: probabilities for false rejection and error detection. *Clin Chem* 1977;23: 1857–1867.
47. Madsen F. Validation of spirometer calibration syringes. *Scand J Clin Lab Invest* 2012;72:608–613.
48. Ruppel GL, Enright PL. Pulmonary function testing. *Respir Care* 2012; 57:165–175.
49. Cooper BG, Steenbruggen I, Mitchell S, Severin T, Oostveen E, Burgos F, *et al*. HERMES spirometry: the European Spirometry Driving Licence. *Breathe (Sheff)* 2011;7:258–275.
50. Steenbruggen I, Mitchell S, Severin T, Palange P, Cooper BG; Spirometry HERMES Task Force. Harmonising spirometry education with HERMES: training a new generation of qualified spirometry practitioners across Europe. *Eur Respir J* 2011;37: 479–481.
51. Swanney MP, O'Dea CA, Ingram ER, Rodwell LT, Borg BM; ANZSRS Spirometry Training Course Working Group. Spirometry training courses: content, delivery and assessment: a position statement from the Australian and New Zealand Society of Respiratory Science. *Respirology* 2017;22:1430–1435.
52. Borg BM, Hartley MF, Fisher MT, Thompson BR. Spirometry training does not guarantee valid results. *Respir Care* 2010;55:689–694.
53. Represas-Represas C, Botana-Rial M, Leiro-Fernández V, González-Silva AI, García-Martínez A, Fernández-Villar A. Short- and long-term effectiveness of a supervised training program in spirometry use for primary care professionals. *Arch Bronconeumol* 2013;49: 378–382.
54. Haynes JM. Quality assurance of the pulmonary function technologist. *Respir Care* 2012;57:114–122. [Discussion, pp. 122–126.]
55. Quanjer PH, Hall GL, Stanojevic S, Cole TJ, Stocks J; Global Lungs Initiative. Age- and height-based prediction bias in spirometry reference equations. *Eur Respir J* 2012;40:190–197.
56. Gauld LM, Kappers J, Carlin JB, Robertson CF. Height prediction from ulna length. *Dev Med Child Neurol* 2004;46:475–480.
57. Quanjer PH, Capderou A, Mazicioglu MM, Aggarwal AN, Banik SD, Popovic S, *et al*. All-age relationship between arm span and height in different ethnic groups. *Eur Respir J* 2014;44:905–912.
58. Braun L, Wolfgang M, Dickersin K. Defining race/ethnicity and explaining difference in research studies on lung function. *Eur Respir J* 2013;41:1362–1370.
59. Quanjer PH, Stanojevic S, Cole TJ, Baur X, Hall GL, Culver BH, *et al*.; ERS Global Lung Function Initiative. Multi-ethnic reference values for spirometry for the 3–95-yr age range: the Global Lung Function 2012 equations. *Eur Respir J* 2012;40:1324–1343.
60. Bucca CB, Carossa S, Colagrande P, Brussino L, Chiavassa G, Pera P, *et al*. Effect of edentulism on spirometric tests. *Am J Respir Crit Care Med* 2001;163:1018–1020.
61. Indrakumar HS, Venkatesh D, Adoni VV, Kashyap R, Jayanthi D, Prakash N. Spirometric assessment of impact of complete dentures on respiratory performance: an *in vitro* study. *J Contemp Dent Pract* 2018;19:177–180.
62. Banerjee SK, Davies M, Sharples L, Smith I. The role of facemask spirometry in motor neuron disease. *Thorax* 2013;68:385–386.
63. Wanger JS, Ikle DN, Cherniack RM. The effect of inspiratory maneuvers on expiratory flow rates in health and asthma: influence of lung elastic recoil. *Am J Respir Crit Care Med* 1996;153:1302–1308.

64. D'Angelo E, Prandi E, Milic-Emili J. Dependence of maximal flow-volume curves on time course of preceding inspiration. *J Appl Physiol (1985)* 1993;75:1155–1159.
65. Stoller JK, Basheda S, Laskowski D, Goormastic M, McCarthy K. Trial of standard versus modified expiration to achieve end-of-test spirometry criteria. *Am Rev Respir Dis* 1993;148:275–280.
66. Stoller JK, McCarthy K. Benefits of a modified spirometry technique. *Eur Respir J* 2007;30:813–814, author reply 814–815.
67. Haynes JM, Kaminsky DA. The American Thoracic Society/European Respiratory Society acceptability criteria for spirometry: asking too much or not enough? *Respir Care* 2015;60:e113–e114.
68. Kozlowska WJ, Aurora P. Spirometry in the pre-school age group. *Paediatr Respir Rev* 2005;6:267–272.
69. Seed L, Wilson D, Coates AL. Children should not be treated like little adults in the PFT lab. *Respir Care* 2012;57:61–70. [Discussion, pp. 71–74.]
70. American Thoracic Society; European Respiratory Society. ATS/ERS statement: raised volume forced expirations in infants: guidelines for current practice. *Am J Respir Crit Care Med* 2005;172: 1463–1471.
71. Newall C, McCauley TM, Shakespeare J, Cooper BG. Is it necessary to use a noseclip in the performance of spirometry using a wedge bellows device? *Chron Respir Dis* 2007;4:53–57.
72. McKibben JM, McKay RT, Freeman AG, Levin LS, Pinney SM, Alshaikh E. Redefining spirometry hesitating start criteria based on the ratio of extrapolated volume to timed FEVs. *Chest* 2011;140:164–169.
73. Müller-Brandes C, Krämer U, Gappa M, Seitner-Sorge G, Hüls A, von Berg A, *et al*. LUNOKID: can numerical American Thoracic Society/European Respiratory Society quality criteria replace visual inspection of spirometry? *Eur Respir J* 2014;43:1347–1356.
74. National Institute for Occupational Safety and Health (NIOSH). Spirometry quality assurance: common errors and their impact on test results. Washington, DC: NIOSH; 2012 [accessed 2019 May 5] DHHS (NIOSH) Publication No. 2012-116. Available from: https://www.cdc.gov/niosh/docs/2012-116/pdfs/2012-116.pdf.
75. Miller MR, Pedersen OF, Quanjer PH. The rise and dwell time for peak expiratory flow in patients with and without airflow limitation. *Am J Respir Crit Care Med* 1998;158:23–27.
76. Glover R, Cooper BG, Lloyd J. Forced expiratory time (FET) as an indicator for airways obstruction. *Eur Respir J* 2014;44:1819.
77. Giner J, Plaza V, Rigau J, Solà J, Bolíbar I, Sanchis J. Spirometric standards and patient characteristics: an exploratory study of factors affecting fulfillment in routine clinical practice. *Respir Care* 2014;59: 1832–1837.
78. Sumphao-Ngern P, Foocharoen C, Boonsawat W, Mahakkanukrauh A, Suwannaroj S, Sae-Oue U, *et al*.; Scleroderma Research Group. Causes and prevalence of inadequate pulmonary function testing among patients with systemic sclerosis. *Arch Med Sci* 2015;11: 1255–1260.
79. Czajkowska-Malinowska M, Tomalak W, Radliński J. Quality of spirometry in the elderly. *Pneumonol Alergol Pol* 2013;81:511–517.
80. Hankinson JL, Eschenbacher B, Townsend M, Stocks J, Quanjer PH. Use of forced vital capacity and forced expiratory volume in 1 second quality criteria for determining a valid test. *Eur Respir J* 2015; 45:1283–1292.
81. Torre-Bouscoulet L, Velázquez-Uncal M, García-Torrentera R, Gochicoa-Rangel L, Fernández-Plata R, Enright P, *et al*. Spirometry quality in adults with very severe lung function impairment. *Respir Care* 2015;60:740–743.
82. Enright P, Vollmer WM, Lamprecht B, Jensen R, Jithoo A, Tan W, *et al*. Quality of spirometry tests performed by 9893 adults in 14 countries: the BOLD Study. *Respir Med* 2011;105:1507–1515.
83. Tan WC, Bourbeau J, O'Donnell D, Aaron S, Maltais F, Marciniuk D, *et al*.; CanCOLD Collaborative Research Group. Quality assurance of spirometry in a population-based study—predictors of good outcome in spirometry testing. *COPD* 2014;11:143–151.
84. Janssens W, Liu Y, Liu D, Kesten S, Tashkin DP, Celli BR, *et al*. Quality and reproducibility of spirometry in COPD patients in a randomized trial (UPLIFT®). *Respir Med* 2013;107:1409–1416.
85. Tomalak W, Radliński J, Latawiec W. Quality of spirometric measurements in children younger than 10 years of age in the light of the recommendations [in Polish]. *Pneumonol Alergol Pol* 2008;76:421–425.
86. Hankinson JL, Bang KM. Acceptability and reproducibility criteria of the American Thoracic Society as observed in a sample of the general population. *Am Rev Respir Dis* 1991;143:516–521.
87. Kirkby J, Welsh L, Lum S, Fawke J, Rowell V, Thomas S, *et al*.; EPICure Study Group. The EPICure study: comparison of pediatric spirometry in community and laboratory settings. *Pediatr Pulmonol* 2008;43: 1233–1241.
88. Enright PL, Beck KC, Sherrill DL. Repeatability of spirometry in 18,000 adult patients. *Am J Respir Crit Care Med* 2004;169:235–238.
89. Gochicoa-Rangel L, Vargas-Domínguez C, García-Mujica ME, Bautista-Bernal A, Salas-Escamilla I, Pérez-Padilla R, *et al*. Quality of spirometry in 5-to-8-year-old children. *Pediatr Pulmonol* 2013;48: 1231–1236.
90. Ferris BG Jr, Speizer FE, Bishop Y, Prang G, Weener J. Spirometry for an epidemiologic study: deriving optimum summary statistics for each subject. *Bull Eur Physiopathol Respir* 1978;14:145–166.
91. Kanner RE, Schenker MB, Muñoz A, Speizer FE. Spirometry in children: methodology for obtaining optimal results for clinical and epidemiologic studies. *Am Rev Respir Dis* 1983;127: 720–724.
92. Barjaktarevic I, Kaner R, Buhr RG, Cooper CB. Bronchodilator responsiveness or reversibility in asthma and COPD: a need for clarity. *Int J Chron Obstruct Pulmon Dis* 2018;13:3511–3513.
93. Davis BE, Blais CM, Cockcroft DW. Methacholine challenge testing: comparative pharmacology. *J Asthma Allergy* 2018;11:89–99.
94. LaForce C, Korenblat P, Osborne P, Dong F, Higgins M. 24-Hour bronchodilator efficacy of single doses of indacaterol in patients with persistent asthma: comparison with placebo and formoterol. *Curr Med Res Opin* 2009;25:2353–2359.
95. Jones TE, Southcott A, Homan S. Drugs potentially affecting the extent of airways reversibility on pulmonary function testing are frequently consumed despite guidelines. *Int J Chron Obstruct Pulmon Dis* 2013; 8:383–388.
96. Enright PL, Lebowitz MD, Cockroft DW. Physiologic measures: pulmonary function tests: asthma outcome. *Am J Respir Crit Care Med* 1994;149:S9–S18. [Discussion, pp. S19–S20.]
97. Ward H, Cooper BG, Miller MR. Improved criterion for assessing lung function reversibility. *Chest* 2015;148:877–886.
98. Quanjer PH, Ruppel GL, Langhammer A, Krishna A, Mertens F, Johannessen A, *et al*. Bronchodilator response in FVC is larger and more relevant than in $FEV_1$ in severe airflow obstruction. *Chest* 2017; 151:1088–1098.
99. Crenesse D, Berlioz M, Bourrier T, Albertini M. Spirometry in children aged 3 to 5 years: reliability of forced expiratory maneuvers. *Pediatr Pulmonol* 2001;32:56–61.
100. Piccioni P, Borraccino A, Forneris MP, Migliore E, Carena C, Bignamini E, *et al*. Reference values of forced expiratory volumes and pulmonary flows in 3-6 year children: a cross-sectional study. *Respir Res* 2007;8:14.
101. Cockcroft DW, Berscheid BA. Volume adjustment of maximal midexpiratory flow: importance of changes in total lung capacity. *Chest* 1980;78:595–600.
102. Swanney MP, Jensen RL, Crichton DA, Beckert LE, Cardno LA, Crapo RO. $FEV_6$ is an acceptable surrogate for FVC in the spirometric diagnosis of airway obstruction and restriction. *Am J Respir Crit Care Med* 2000;162:917–919.
103. Vandevoorde J, Verbanck S, Schuermans D, Kartounian J, Vincken W. $FEV_1/FEV_6$ and $FEV_6$ as an alternative for $FEV_1$/FVC and FVC in the spirometric detection of airway obstruction and restriction. *Chest* 2005;127:1560–1564.
104. Kainu A, Lindqvist A, Sarna S, Sovijärvi A. Intra-session repeatability of FET and $FEV_6$ in the general population. *Clin Physiol Funct Imaging* 2008;28:196–201.
105. Bellia V, Sorino C, Catalano F, Augugliaro G, Scichilone N, Pistelli R, *et al*. Validation of $FEV_6$ in the elderly: correlates of performance and repeatability. *Thorax* 2008;63:60–66.
106. Perez-Padilla R, Wehrmeister FC, Celli BR, Lopez-Varela MV, Montes de Oca M, Muiño A, *et al*.; PLATINO Team. Reliability of $FEV_1/FEV_6$ to diagnose airflow obstruction compared with $FEV_1$/FVC: the PLATINO longitudinal study. *PLoS One* 2013;8: e67960.

107. Akpinar-Elci M, Fedan KB, Enright PL. $FEV_6$ as a surrogate for FVC in detecting airways obstruction and restriction in the workplace. *Eur Respir J* 2006;27:374–377.
108. Hankinson JL, Odencrantz JR, Fedan KB. Spirometric reference values from a sample of the general U.S. population. *Am J Respir Crit Care Med* 1999;159:179–187.
109. Hansen JE, Porszasz J, Casaburi R, Stringer WW. Re-defining lower limit of normal for $FEV_1/FEV_6$, $FEV_1/FVC$, $FEV_3/FEV_6$ and $FEV_3/FVC$ to improve detection of airway obstruction. *Chronic Obstr Pulm Dis* 2015;2:94–102.
110. Marsh S, Aldington S, Williams M, Weatherall M, Shirtcliffe P, McNaughton A, *et al*. Complete reference ranges for pulmonary function tests from a single New Zealand population. *N Z Med J* 2006;119:U2281. [Published erratum appears in *N Z Med J* 120: U2551.]
111. Tian XY, Liu CH, Wang DX, Ji XL, Shi H, Zheng CY, *et al*. Spirometric reference equations for elderly Chinese in Jinan aged 60-84 Years. *Chin Med J (Engl)* 2018;131:1016–1022.
112. Raposo LB, Bugalho A, Gomes MJ. Contribution of flow-volume curves to the detection of central airway obstruction. *J Bras Pneumol* 2013;39:447–454.
113. Modrykamien AM, Gudavalli R, McCarthy K, Liu X, Stoller JK. Detection of upper airway obstruction with spirometry results and the flow-volume loop: a comparison of quantitative and visual inspection criteria. *Respir Care* 2009;54: 474–479.
114. Culver BH, Graham BL, Coates AL, Wanger J, Berry CE, Clarke PK, *et al*.; ATS Committee on Proficiency Standards for Pulmonary Function Laboratories. Recommendations for a standardized pulmonary function report: an Official American Thoracic Society technical statement. *Am J Respir Crit Care Med* 2017;196: 1463–1472.
115. Salas T, Rubies C, Gallego C, Muñoz P, Burgos F, Escarrabill J. Technical requirements of spirometers in the strategy for guaranteeing the access to quality spirometry. *Arch Bronconeumol* 2011;47:466–469.
116. Goel A, Goyal M, Singh R, Verma N, Tiwari S. Diurnal variation in peak expiratory flow and forced expiratory volume. *J Clin Diagn Res* 2015;9:CC05–CC07.
117. Fregonezi G, Resqueti VR, Cury JL, Paulin E, Brunetto AF. Diurnal variations in the parameters of pulmonary function and respiratory muscle strength in patients with COPD. *J Bras Pneumol* 2012;38: 257–263.
118. Johnston R. PFT blog: a modest proposal for a clinical spirometry grading system. 2018 Sep 16 [accessed 2019 May 5]. Available from: https://www.pftforum.com/blog/a-modest-proposal-for-a-clinical-spirometry-grading-system/#more-2420.
119. British Thoracic Society; Association of Respiratory Technology and Physiology. Guidelines for the measurement of respiratory function: British Thoracic Society and the Association of Respiratory Technology and Physiology. *Respir Med* 1994;88:165–194.
120. Babb TG, Viggiano R, Hurley B, Staats B, Rodarte JR. Effect of mild-to-moderate airflow limitation on exercise capacity. *J Appl Physiol (1985)* 1991;70:223–230.
121. O'Donnell DE, Lam M, Webb KA. Spirometric correlates of improvement in exercise performance after anticholinergic therapy in chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1999;160:542–549.
122. Pellegrino R, Rodarte JR, Brusasco V. Assessing the reversibility of airway obstruction. *Chest* 1998;114:1607–1612.
123. Younes M, Kivinen G. Respiratory mechanics and breathing pattern during and following maximal exercise. *J Appl Physiol* 1984;57: 1773–1782.
124. Wanger J, Clausen JL, Coates A, Pedersen OF, Brusasco V, Burgos F, *et al*. Standardisation of the measurement of lung volumes. *Eur Respir J* 2005;26:511–522.
125. Brusasco V, Pellegrino R, Rodarte JR. Vital capacities in acute and chronic airway obstruction: dependence on flow and volume histories. *Eur Respir J* 1997;10:1316–1320.
126. Hansen LM, Pedersen OF, Lyager S, Naerra N. Differences in vital capacity due to the methods employed. *Ugeskr Laeger* 1983;145: 2752–2756.
127. Borg BM, Thompson BR. The measurement of lung volumes using body plethysmography: a comparison of methodologies. *Respir Care* 2012;57:1076–1083.
128. Russell AM, Adamali H, Molyneaux PL, Lukey PT, Marshall RP, Renzoni EA, *et al*. Daily home spirometry: an effective tool for detecting progression in idiopathic pulmonary fibrosis. *Am J Respir Crit Care Med* 2016;194:989–997.
129. Wang W, Finkelstein SM, Hertz MI. Automatic event detection in lung transplant recipients based on home monitoring of spirometry and symptoms. *Telemed J E Health* 2013;19:658–663.
130. Murgia F, Bianciardi F, Solvoll T, Tagliente I, Bella F, Carestia A, *et al*. Telemedicine home program in patients with cystic fibrosis: results after 10 years. *Clin Ter* 2015;166:e384–e388.
131. Burgos F, Disdier C, de Santamaria EL, Galdiz B, Roger N, Rivera ML, *et al*.; e-Spir@p Group. Telemedicine enhances quality of forced spirometry in primary care. *Eur Respir J* 2012;39: 1313–1318.
132. Marina Malanda N, López de Santa María E, Gutiérrez A, Bayón JC, Garcia L, Gáldiz JB. Telemedicine spirometry training and quality assurance program in primary care centers of a public health system. *Telemed J E Health* 2014;20:388–392.
133. Weiner DJ, Forno E, Sullivan L, Weiner GA, Kurland G. Subjective and objective assessments of flow-volume curve configuration in children and young adults. *Ann Am Thorac Soc* 2016;13: 1089–1095.
134. Dominelli PB, Foster GE, Guenette JA, Haverkamp HC, Eves ND, Dominelli GS, *et al*. Quantifying the shape of the maximal expiratory flow-volume curve in mild COPD. *Respir Physiol Neurobiol* 2015; 219:30–35.
135. Stuart-Andrews CR, Kelly VJ, Sands SA, Lewis AJ, Ellis MJ, Thompson BR. Automated detection of the phase III slope during inert gas washout testing. *J Appl Physiol (1985)* 2012;112: 1073–1081.
136. Anogeianaki A, Negrev N, Ilonidis G. Contributions of signal analysis to the interpretation of spirometry. *Hippokratia* 2007;11:187–195.
137. Lian N, Li L, Ren W, Jiang Z, Zhu L. Angle β of greater than 80° at the start of spirometry may identify high-quality flow volume curves. *Respirology* 2017;22:527–532.
138. Melia U, Burgos F, Vallverdú M, Velickovski F, Lluch-Ariet M, Roca J, *et al*. Algorithm for automatic forced spirometry quality assessment: technological developments. *PLoS One* 2014;9:e116238.
139. Luo AZ, Whitmire E, Stout JW, Martenson D, Patel S. Automatic characterization of user errors in spirometry. *Conf Proc IEEE Eng Med Biol Soc* 2017;2017:4239–4242.
140. Velickovski F, Ceccaroni L, Marti R, Burgos F, Gistau C, Alsina-Restoy X, *et al*. Automated spirometry quality assurance: supervised learning from multiple experts. *IEEE J Biomed Health Inform* 2018; 22:276–284.
141. Morris ZQ, Coz A, Starosta D. An isolated reduction of the $FEV_3/FVC$ ratio is an indicator of mild lung injury. *Chest* 2013; 144:1117–1123.
142. Bhatt SP, Kim YI, Wells JM, Bailey WC, Ramsdell JW, Foreman MG, *et al*. $FEV_1/FEV_6$ to diagnose airflow obstruction: comparisons with computed tomography and morbidity indices. *Ann Am Thorac Soc* 2014;11:335–341.
143. Dilektasli AG, Porszasz J, Casaburi R, Stringer WW, Bhatt SP, Pak Y, *et al*.; COPDGene investigators. A novel spirometric measure identifies mild COPD unidentified by standard criteria. *Chest* 2016; 150:1080–1090.
144. Ioachimescu OC, Venkateshiah SB, Kavuru MS, McCarthy K, Stoller JK. Estimating FVC from $FEV_2$ and $FEV_3$: assessment of a surrogate spirometric parameter. *Chest* 2005;128:1274–1281.
145. Miller MR, Grove DM, Pincock AC. Time domain spirogram indices: their variability and reference values in nonsmokers. *Am Rev Respir Dis* 1985;132:1041–1048.
146. Liu C, Yang Y, Tsow F, Shao D, Tao N. Noncontact spirometry with a webcam. *J Biomed Opt* 2017;22:57002.
147. Coates AL, Wanger J, Cockcroft DW, Culver BH, Carlsen KH, Diamant Z, *et al*. ERS technical standard on bronchial challenge testing: general considerations and performance of methacholine challenge tests. *Eur Respir J* 2017;49:1601526.