La Medicina del Lavoro

Med Lav 2021; 112, 2: 95-106
DOI: 10.23749/mdl.v112i2.11420

Conducting spirometry in occupational health at COVID-19 times: international standards

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Keywords: Spirometry; occupational health; spirometry standards; COVID-19 pandemic

Summary
Spirometry is a commonly performed assessment of lung function for diagnostic purposes as well as for monitoring of chronic lung diseases. The last international standardization of this technique was published in 2005. After 14 years, a group of experts from two leading scientific societies, American Thoracic Society (ATS) and European Respiratory Society (ERS), published a joint position that updated the standardization of spirometry, with an extensive criteria re-organization, including key updates such as: relative contraindications, instrumentation requirement to meet the International Organization for Standardization (ISO) standards, quality assurance, operator training, pre-test requirements, acceptability and usability criteria. New standards underline three key elements to obtain high quality pulmonary function data: an 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. Nevertheless, although COVID-19 pandemic has enormously impacted and limited a widespread application of spirometry, it has prompted much attention on hygienic procedures and on further research on noncontact spirometers.

Introduction

The history of spirometry starts almost 200 years ago with James Hutchinson, who developed the spirometer "*with a view of establishing a precise and easy method of detecting disease*" (1). Quite surprisingly, his studies about pulmonary physiology started with occupational medicine. In fact, Hutchinson performed physical examination of workers for an insurance company, in order to determine whether they could work as coal miners or not (2); with this background, he worked out the idea of the spirometer to clarify decisions about respiratory health, which he considered necessary for that job (1). Most national and international healthcare guidelines nowadays endorse spirometry as best practice for measuring lung function (3, 4).

In occupational medicine, spirometry is still widely used to screen workers for their ability to perform certain tasks or efforts, and to evaluate workers' respiratory health in medical surveillance programs. Therefore, spirometry results can play a central role after hiring, in decisions about worker job assignments, in use, choice and efficacy assess-

Financial support: no financial support was granted to this work.

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ment of personal protective equipment (PPE), and also in the assessment of exposure-related health effects (5). What is more, a recent milestone article reported that occupational exposure is a potential cause of almost all respiratory diseases. In fact, workplace exposures contribute substantially to the burden of multiple chronic respiratory diseases, including asthma (16%), chronic obstructive pulmonary disease (14%), chronic bronchitis (13%), idiopathic pulmonary fibrosis (26%), hypersensitivity pneumonitis (19%), other granulomatous diseases, including sarcoidosis (30%), pulmonary alveolar proteinosis (29%), tuberculosis (2.3% in silica-exposed workers and 1% in healthcare workers), and community-acquired pneumonia in working-age adults (10%) (6).

Lung function testing has become more and more important even in general practice settings, and it is now recognized as a measure of global health, predicting all-cause mortality and morbidity in adults (7–9). MyLinh Duong and colleagues provide evidence supporting a relationship between impaired lung function and respiratory and cardiovascular abnormalities and death, with data from their prospective epidemiology study (10). In addition, lung function test results and changes in lung function over time have been shown to identify patients at high risk for lung cancer (11, 12).

From the evidence reviewed above, spirometry could also be considered a health biomarker because it can identify a group of individuals at risk of suffering from non-communicable diseases (not only respiratory diseases) and premature mortality. In any case, it is remarkable that the original description of the spirometer almost 200 years ago by Hutchinson included the term *"vital"* capacity: he first coined the definition of "*vital*" capacity, originally described as "…the greatest voluntary expiration following the deepest inspiration". According to the latest evidence, which supports spirometry as a valuable and dynamic contribution for health monitoring in a wide range of situations, from physiology research to general practice, the definition of "vital capacity" provided by Hutchinson becomes even more fitting for such a multipurpose parameter.

The importance of spirometry has nowadays become even greater during the ongoing pandemic emergency. In fact, as regards patients recovered from COVID-19 who are experiencing persistent or evolving respiratory complications, guidelines propose a detailed follow-up (13): all patients recovered from a severe or a mild-to-moderate pneumonia, or clinically improved patients with persistent changes in the chest X-ray 12 weeks post-discharge, should undergo pulmonary function tests.

In addition, patients with chronic diseases are contacting physicians to inquire when they can return to work safely, and employers are posing similar questions. Therefore, spirometry testing in occupational health could represent an exceptional, non-invasive, and highly effective method of monitoring lung capacity and wellness of employees.

Whether spirometry is performed to comply with workplace-mandated programs, in the context of health promotion or in return-to-work recommendation, its value is compromised when testing is conducted incorrectly, equipment is inadequate, or results are misinterpreted. Technically flawed tests too often lead to inaccurate interpretations of worker respiratory health, falsely labelling normal subjects as "impaired" or impaired subjects as "normal." Such flawed test results are not only useless but also convey false information which could be harmful to workers (14). What is more, outdated technology built into older spirometers, their bulkiness and the fragility of these devices represent a significant hurdle for occupational physicians, who work outside lung function laboratories.

In 2005, the American Thoracic Society (ATS) and the European Respiratory Society (ERS) jointly adopted technical standards for conducting spirometry (15). After 14 years, a group of experts from these two respiratory scientific societies published a joint position that updated the standardization of spirometry (16). The 2019 Spirometry Standards have been extensively re-organized with numerous updates which will be discussed in this document. As this document was last updated many years ago, this long-awaited update is of capital relevance for those occupational physicians who will practice spirometry from here forward.

Interestingly, among the indications for spirometry, in the new Standards it has been added: "*preemployment and lung health monitoring for at-*

risk occupations", thus stressing the critical role of spirometry in primary, secondary, and tertiary prevention of workplace-related lung disease.

The main applications of spirometry in occupational health are then listed below:

– To establish baseline values and assess longitudinal trend/decline
– To monitor workers at risk of having pulmonary disease due to workplace exposure
– To monitor efficacy of PPE
– For an appropriate job placement
– To diagnoses occupational lung disease
– For return to work after pulmonary disease
– To assess workers' capability to perform heavy exertion
– To assess individuals for legal reasons
– To monitor progression of an established disease
– In health promotion and research programs.

The current commentary will provide an overview of main changes and novelties present in the new spirometry standard document.

Contraindications

Contraindications were previously mentioned (but not addressed in detail) in the 2005 General Consideration document (17) rather than the 2005 Spirometry Standards; contraindications have been extensively updated and expanded in the 2019 update. In general, contraindications can be considered as 'relative' or 'absolute'. Of note, all the contraindications in the 2019 update have remarkably been defined as relative (none is absolute), which would mean that they do not preclude spirometry, but each case should be carefully considered in the preliminary phase. However, patients with potential contraindications that would prevent testing in primary care setting (as it often happens in occupational medicine) might be tested in a pulmonary function laboratory, where operators are more experienced and there may be access to emergency care if needed. The forced expiratory maneuver required in spirometry may result, in fact, in increased intrathoracic, intraabdominal, and intracranial pressures. Thus, a check list including all the relative contraindications included in the box below must be completed before testing (16).

- Acute myocardial infarction within 1 week
- Systemic hypotension or severe hypertension
- Significant atrial/ventricular arrhythmia
- Non-compensated heart failure
- Uncontrolled pulmonary hypertension
- Acute cor-pulmonale
- Unstable pulmonary embolism
- History of syncope during forced expiration/cough
- Cerebral aneurysm
- Bra in surgery within 4 weeks
- Recent concussion with continuing symptoms
- Eye surgery within 1 week
- Sinus surgery or ear surgery or infection within 1 week
- Presence of pneumothorax
- Thoracic surgery within 4 weeks
- Abdominal surgery within 4 weeks
- Late term pregnancy
- Transmissible respiratory or systemic infections

It is worth noting that the presence of aortic aneurysms and significant glaucoma, both cited in previous consensus documents (18), are not listed among contraindications. Furthermore, the previous contraindication of spirometry testing within 1 month of a myocardial infarction has been reduced to 1 week. In addition, there were items mentioned in the body of text not listed in the table: "*Spirometry should be discontinued if the patient experiences pain during the maneuver.*" "*…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.*"

Many contraindications represent a higher risk situation with tests involving forced maneuvers; therefore, options could be considered such as performing less forced tests such as oscillometry and relaxed vital capacity (also defined slow vital capacity, SVC) (19).

Among contraindications, patient having active or suspected transmissible respiratory or systemic infection is reported; in COVID-19 era, this point is crucial. Latest ERS document does not recommend any patients with symptoms of COVID-19, or flu-like, to be tested under any circumstances in

high prevalence areas (20). This is in agreement with American College of Occupational and Environmental Medicine (ACOEM) guidance document (21).

Hygiene and infection control

This topic was addressed in the 2019 update document, but it received additional importance in the context of SARS-CoV-2 infection, being examined by a recent ERS recommendation about lung function testing during COVID-19 pandemic (20). In fact, spirometry test often generates aerosols and droplets due to patients' cough and exhalations, and therefore it poses a considerable risk for the spread of infections to operators, and for cross-contamination of surrounding surfaces within and around the test area, even in presence of asymptomatic patients.

There are three main potential sources of cross-contamination when performing the test: skin contact, aerosolized particles and saliva/body fluids droplets; therefore, hygiene measures to protect users and operators are crucial. However, recommended safety measures will negatively affect testing times and patients' flow: ERS group 9.1 recommendations state as mandatory pre-test COVID-19 status screening of patients, hand hygiene for staff and users, surfaces decontamination after each test (followed by recalibration of equipment), single-use PPE and equipment disposing, test room ventilation (20). The same document identifies three levels of safety recommendations, according to local community prevalence of the infection (20):

1. Level 1: pandemic phase: only essential tests should be performed. These circumstances require organizational, testing and infection control measures (20). The choice of using disposable equipment such as nose-clips and mouthpieces is strongly recommended; after testing, they should be removed by staff using gloves (16) and disposed in bins for infectious waste. If the equipment includes reusable items, they should be carefully removed wearing single-use gloves and cleaned as stated in local infection control policies.
2. Level 2: post peak phase: even if viral circulation is lower than in the pandemic phase, the recommendations about organization and infection control remain the same as in pandemic phase (20).
3. Level 3: post pandemic phase: since viral circulation is controlled, it is possible to return to pre-COVID-19 standards (20).

Thus, during periods of high prevalence of infection in the community, referring personnel must carefully consider the safety of staff/patient and cross-contamination of equipment.

A study assessed the efficacy of a single-use bacterial/viral filter for the prevention of equipment contamination during pulmonary function assessment (22). The outcome of the study, which included two groups of patients (infectious and non-infectious), showed that it was very important to use filters when performing pulmonary function tests as bacteria, including pathogenic organisms, can freely be transmitted to equipment.

Three steps are consequently critical:

- Hand hygiene for patients and staff according to local infection control policy (if combined with use of disposable gloves, they should be worn during testing and cleaning procedures, then removed and followed by hand hygiene), PPE use for Healthcare Workers (HCWs) performing tests, specifying that HCWs should wear filtering facepiece FFP3 (FFP2 if not available) and eye protection (20). In addition, HCWs should wear a full gown (i.e., covering shoulders and lower arms) (23).
- Spirometry should always be carried out with a high specification disposable in-line bacterial and viral filter in place. Filters must have 3 characteristics:
  a. efficacy of filtration, which is calculated by determining the airborne concentration of viable micro-organisms upstream and downstream of the filter using suitable aerosol sampling techniques and microbial assay methods. A 99.99% efficient bacterial/viral filter even for high expiratory flow of 600-700 L/min is requested (20);
  b. the total resistance of the filter and lung respiratory tube function instrument should be < 1.5 cm H_2O at a flow rate of 14 L^*s^{-1}, in order to not affect the results of the lung function test;
  c. the dead space of the bacterial/viral filter should be as small as possible, in order that no detriment to the breathing work is experienced by the patient. Currently, manufacturers supplying bacterial/viral filters for pulmonary function testing equipment can offer dead spaces of

between 50–75 mL on their equipment.
- Equipment cleaning with 75 % ethanol for 3 min twice is recommended (24), then recalibrate lung function equipment after decontamination (20). The use of disposable combined sensors is not recommended at this time based on latest ERS indications.

In addition, further considerations for conducting spirometry during pandemic phase must be reported: it is mandatory to maximize distance between the patient and HCWs, to remove all unnecessary equipment from the room and, not less important, to use a separate room, designated only for spirometry testing, and equipped with proper ventilation with 15–30-minute open window after each test (24).

Patient details

According to the 2005 Standards, only smoking was indicated as an activity that should be avoided prior to testing. The 2019 Standards indicates a number of additional activities to be avoided before performing spirometry: smoking electronic cigarettes (to avoid acute bronchoconstriction due to smoke inhalation) and consumption of intoxicants (to avoid problems with coordination, understanding and physical performance) were added. Both additional indications could be of particular importance in occupational medicine, when spirometries are performed in the workplaces: avoid vigorous exercise within 1 hr prior to testing (to avoid potential exercise-induced bronchoconstriction) and wearing clothing that substantially restricts full chest and abdominal expansion (to avoid external restrictions on lung function). Some working activities are indeed physically demanding, and safety uniforms might induce external restriction.

Furthermore, patient testing considerations have been expanded and now includes: "*Testing should preferably occur in a quiet and comfortable environment that is separated from the waiting room and from other patients being tested*" and "*Drinking water should be available. Tissues or paper towels should be offered to help patients deal with secretions*."

The document emphasizes that the patient performing the exam should be seated erect, with shoulders slightly back and chin slightly elevated. This recommendation is due to the fact that syncope is the most common undesirable effect of spirometry. A chair with arms, without wheels, and with a height adjustment, so that the feet are flat on the floor, should be used.

Patient details now include the statement "*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*." Age must be in years to the nearest one decimal place, height in centimeters to one decimal point and weight to the nearest 0.5 kg.

Personnel qualification

Standard states that spirometry should be performed by trained and experienced personnel, able to assess the correct performance of tests by patients and to assure good quality of results. The operator is responsible for monitoring the exam, and for interaction with the patient to achieve optimal results, requiring a combination of training and experience.

Latest guidelines stress the importance of quality training and continuing education programs that certify the expertise: "Operator training and attainment and maintenance of competency must be integrated into any spirometry testing service". In the United States, Occupational Safety and Health Administration (OSHA) requires that technicians performing spirometry for certain occupational indications complete a training course and following updates (25).

Two studies, in the Netherlands and Spain respectively, have suggested that greater accuracy is obtained in pulmonary function laboratories than in primary care (26, 27), but a study in New Zealand found that a training package had only modest results (28).

In Italy there is no professional figure of the respiratory physiopathology technician, thus spirometry is often carried out with the help of nurses, generic technicians or physicians. The ERS has designed a training procedure, the European Spirometry Driving License, which was launched in 2012 (29).

Spirometers

In the 2019 update, it is reported that manufacturers must ensure that all spirometers meet the standards contained in the current update of ISO 26782 (Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans), update 2009. The standard for spirometers ISO 26782:2009 states, in the section on performance requirement: "*that the maximum permissible error for the volume reading in the measurement range shall be ± 2,5 % of reading*"; thus, the update of 2019 has reduced the accuracy error from ± 3 % as stated in the 2005 standard to ± 2.5 %.

When purchasing spirometers and their software, the seller should confirm that devices have undergone validation testing by a competent and properly equipped testing laboratory to demonstrate that they meet the ISO standards (the ISO standard for spirometers is a legal requirement for Conformité Européenne (CE) Marked devices).

Ambient temperature, barometric pressure, and time of day must be recorded. This was mandatory in the 2005 General Considerations and it is still included in the 2019 Spirometry Standards.

Calibration

Information was also added about the required accuracy of the 3 L calibration syringe, which should be within ± 0.5%, giving in practice the accuracy of the entire calibration process at the current recommended level of ± 3% (2.5% spirometer tolerance plus 0.5% calibration syringe tolerance). Manufacturers are now required to provide an alert if a calibration is ± 2 SD from the mean calibration factor or ± 6% from the previous calibration factor.

Quality assurance now includes the statement "*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*". Quality assurance now includes also "*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*".

The 2019 Standard states that "*The spirometry system must determine the zero-flow level with the spirometer blocked before calibration, calibration verifications, and patient tests*". Zero-flow levels were not discussed in the 2005 Standards.

An important difference from the 2005 Standards is that three-stream calibration check (carried out by the movements of the piston of the calibration syringe with three different speeds) should now be daily (previously weekly).

Biological quality control is mentioned but it is also indicated that "*A biological control is not a substitute for the use of a calibration syringe*" and that "*In some jurisdictions, including a biological control in quality control reporting may constitute a breach of employee privacy protection*".

Forced vital capacity (FVC) maneuver

Whereas previous guidelines were more focused on volume measurement devices using the expiration-only technique, the 2019 update focused on inspiratory and expiratory flow. Both the 2005 and 2019 Spirometry Standards indicate that the maximum number of FVC maneuvers in adults should be eight.

The new standards see the FVC maneuver to be comprised of four distinct phases: i) maximal inspiration, ii) a 'blast' of expiration, iii) continued complete expiration for a maximum of 15 seconds, and iv) inspiration at maximal flow back to maximum lung volume (Fgure 1). The fourth phase was not present in the 2005 Standards.

i) Maximal inspiration

Guideline requires a rapid inhalation to Total Lung Capacity (TLC) with a pause (hesitation) ≤ 2 seconds before expiration. Hesitation time, which is not mentioned in the 2005 Standards, is "*…defined as the time from the point of maximal inspiration to Time 0*". A hesitation in blowing out before the initial blast affects most spirometry test results early in the maneuver. A hesitating start creates a high back extrapolated volume (BEV); BEV error is now 0.100 L (not 0.150 L anymore) and still <5 % FVC whichever is greater (16). Traditionally, the 5 % of FVC is more applicable in occupational medicine settings. A large BEV will usually result in an er-

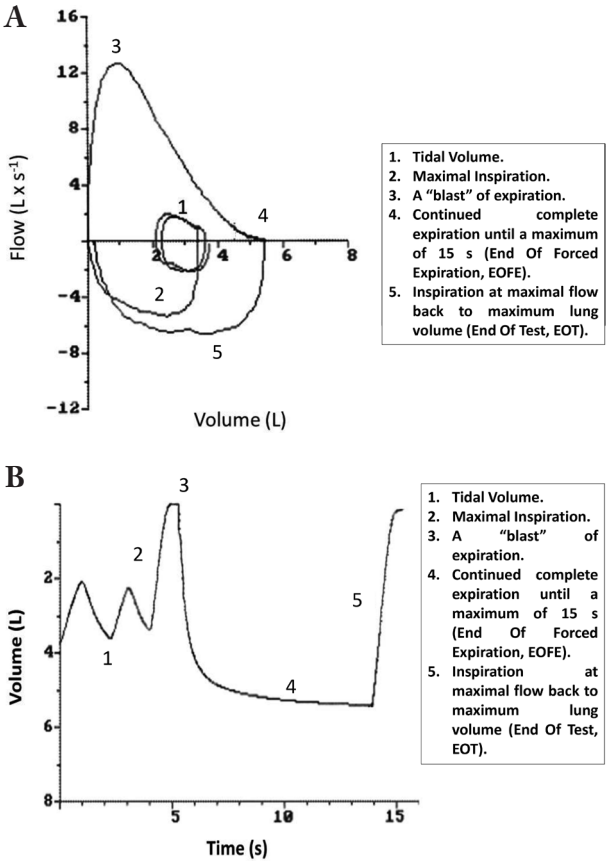

Figure 1: A) Phases of spirogram, Flow/Volume Curve. B) Phases of spirogram, Volume/Time Curve

roneously high forced expiratory volume in the first second (FEV_1).

ii) A blast of expiration

The second phase of the spirometry maneuver is to blast out the air as quickly as possible, thereby achieving a "sharp" peak flow during the first tenth of a second and a high average flow during the first second of the maneuver. The rise time from 10% to 90% of peak flow should be ≤ 150 ms, and this was not reported in the previous guidelines, but it was present in former ATS documents (30).

iii) End of Forced Exhalation (EOFE)

Before the 2019 update, a patient was expected to perform a forced expiratory maneuver that lasted at least 6 seconds. The current update states that the EOFE is no longer defined by a 6-second minimum forced expiration time (FET). End of Test (EOT) acronym has been replaced with EOFE since the end of forced expiration is not the end of the maneuver, and hence the term EOFE is used. Thus, there is not a minimum FET. One of the following three may signal an EOFE must be applied: i) an expiratory plateau (≤ 0.025 L in the last 1 s of expiration) or ii) when FET ≥ 15 s or iii) when patient cannot/does not reach plateau. An expiratory plateau is the most reliable indicator of complete expiration. In the 2019 Standard it is mandatory that "*The spirometry system must signal the operator when a plateau has been reached or forced expiratory time (FET) reaches 15 seconds*".

iv) Maximal inspiration after forced expiration

FVC maneuver now includes a fourth phase "*inspiration at maximal flow back to maximum lung volume*", thus the measurement of the forced inspiratory vital capacity (FIVC). It is a maximal effort to return to TLC and complete the flow–volume loop. However, it is worth noting that the current standards also indicate an important role (and recommend performing) of maneuver after the FVC maneuver in order to verify the correctness of the inspiration preceding the forced exhalation. The difference between FIVC and FVC (FIVC-FVC) must be less than 0.1 L or <5% of FVC whichever is greater (FIVC).

The proper forced expiratory maneuver, which is shown in Figure 1, must be then performed according to the following list:

A. Prepare the patient (check hygiene, anthropometrics, medication use, contraindications, pre-test smoking/use of intoxicants/physical activity/constricting clothes, respiratory symptoms).
B. Instruct and demonstrate the test (mouthpiece, nose clip, posture).
C. Perform maneuver:
   - Have patient assume the correct posture
   - Attach nose clip and close lips around mouthpiece
   - Breath normally
   - Inspire completely and rapidly with a pause of ≤ 2 s at TLC
   - Expire with maximal effort until no more air can be expelled
   - Inspire with maximal effort until completely full
   - Repeat instructions as necessary, coaching vigorously and helping with gestures
   - Repeat for a minimum of three maneuvers, usually no more than eight for adults, with proper rest pauses for patient

– Check FEV_1 and FVC repeatability and perform more maneuvers if necessary

D. Remove nose clip and check patient well-being.

Table 1 reports the main differences between previous and current guidelines. Figure 2 summarizes the key points for quality assessment of spirometry.

Acceptability, Repeatability and Usability

The goal of the test session is to achieve a minimum of three acceptable FEV_1 and three acceptable FVC measurements. Repeatability is based on the difference between the two largest, acceptable FEV_1 and FVC, regardless of whether they were from the same or different maneuvers. For subjects over 6 years old the difference must be less than or equal to 150 ml.

Achieving repeatable results is the best indicator that the patient performed the maximal FEV_1 and FVC that she or he was able to do. The degree of repeatability, which is quantified in the grading system, guides the confidence level in the interpretation of results.

FEV_1 and FVC are now to be individually evaluated for acceptability rather than a maneuver as a whole. An acceptable FEV_1 from a maneuver can now be reported regardless of the quality of the FVC and *vice versa*. The concept of 'usable' is also introduced, whereby a technically unacceptable measurement can still be clinically useful. This happens when the subjects have performed the best they are able on this occasion, but the maneuvers do not meet all the criteria (Table 2).

Table 1. Key updates comparison between former and updated guidelines

		Miller 2005 (15)	*Graham 2019 (16)*
Contraindications		Not addressed	Reported
Personnel qualification		Not addressed	Reported
Calibration	Volume accuracy Linearity check	Daily Weekly	Daily Daily
Quality of spirometers		Not addressed	ISO 26782
Spirometer accuracy		3%	2.5%
To be avoided prior to testing		Cigarette smoking	Smoking and/or vaping and/or water pipe use Consuming intoxicants Vigorous exercise Wearing tight clothing
Test procedure for FVC		3 phases	4 phases
Phase 1: Inhalation to TLC	Hesitation Back extrapolation value	Minimal hesitation 0.15 L or 5% of FVC	≤ 2 sec 0.1 L or 5% of FVC
Phase 2 and 3: maximal expiration	Time to peak (rise time from 10% to 90% of peak flow)	Non reported	<150 ms
	Minimum FET	At least 6 seconds	Non reported
	End of the test criteria	EOT: Plateau <0.025 L for 1 s, and ≥ 6 seconds of FET or If the subject cannot or should not continue to exhale	EOFE: A FET of 15 s or Plateau: < 25 mL change in volume for ≥1 s or The patient cannot expire long enough to achieve a plateau
Phase 4: Maximal inspiration after FVC		Not requested	Requested FIVC-FVC must be less than 0.1 L

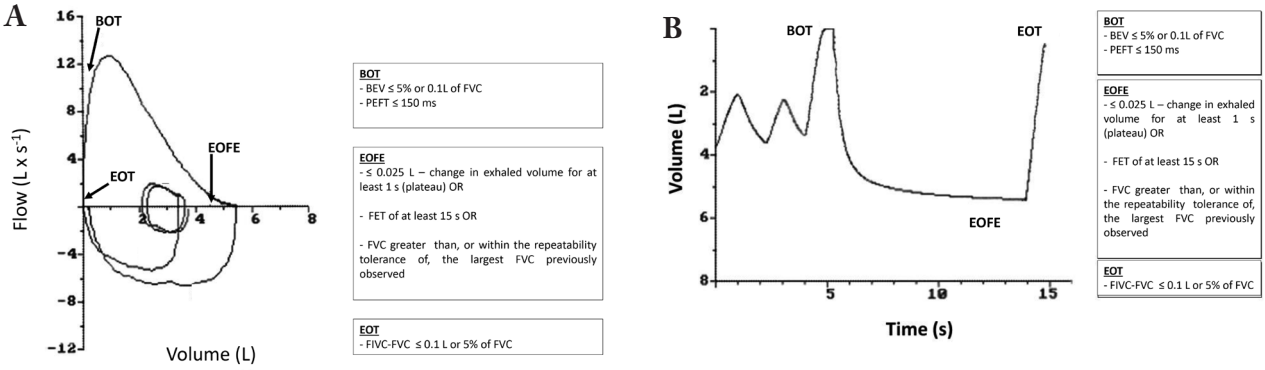

Figure 2: A) Key points for quality assessment of Flow/Volume curve. *BOT: Beginning Of Test; BEV: Back Extrapolated Volume; FVC: Forced Vital Capacity; PEFT: Time of Peak Expiratory Flow; EOFE: End Of Forced Expiration; FET: Forced Expiratory Time; EOT: End Of Test; FIVC: Forced Inspiratory Vital Capacity.* B) Key points for quality assessment of Volume/Time curve. *BOT: Beginning Of Test; BEV: Back Extrapolated Volume; FVC: Forced Vital Capacity; PEFT: Time of Peak Expiratory Flow; EOFE: End Of Forced Expiration; FET: Forced Expiratory Time; EOT: End Of Test; FIVC: Forced Inspiratory Vital Capacity.*

Table 2. Acceptability and usability criteria

	Required for Acceptability		Required for Usability	
	FEV_1	FVC	FEV_1	FVC
Must have back extrapolated volume ≤5% of FVC or 0.100 L, whichever is greater	+	+	+	+
Must have no evidence of a faulty zero-flow setting	+	+	+	+
Must have no glottis closure in the first second of expiration	+	+	+	+
Must achieve one of three end of forced expiration indicators	-	+	-	-
Must have no evidence of obstructed mouthpiece or spirometer	+	+	-	-
Must have no evidence of a leak	+	+	-	-
Must have no cough in the first second of expiration	+	-	+	-
If the maximal inspiration following end of forced expiration is >FVC, then FIVC – FVC must be ≤ 0.100 L or 5% of FVC, whichever is greater	+	+	-	-

Modified from ref. (16)

Grading the Quality of the Test Session

Technical standards are designed to help attain the best result possible for each patient. Spirometry results rely completely on patient cooperation. Maneuvers done at maximal lung volume with maximal effort are more repeatable than maneuvers performed at submaximal lung volumes or with submaximal effort.

The grading system that is recommended for spirometry reporting is shown in Table 3. This grading system informs the interpreter about the level of

Table 3. Grading System for FEV_1 and FVC (Graded Separately)

Grade	Number of Measurements	Repeatability
A	>3 acceptable	Within 0.150 L
B	2 acceptable	Within 0.150 L
C	>= 2 acceptable	Within 0.200 L
D	>= 2 acceptable	Within 0.250 L
E	>= 2 acceptable OR 1 acceptable	> 0.250 L Not Applicable
U	0 acceptable AND >= 1 usable	Not Applicable
F	0 acceptable and 0 usable	Not Applicable

Modified from ref. (16)

confidence that the spirometry results represent the best that the patient/worker was able to do at the time of the test and that an equivalent value would be achieved with a certain probability if the test should be repeated. Some patients/workers may not be able to meet the criteria for acceptability and repeatability that are necessary for grade A, but nevertheless, their results may be useful. Although some maneuvers may be acceptable or usable at grade levels lower than A, the overriding goal of the operator must be to achieve the best possible testing quality ever for each patient/worker.

Reference Values and Longitudinal Interpretation

After establishing their technical validity, spirometry results are evaluated at the time of the test, comparing the subject's results with the normal range expected for his/her current demographic characteristics. The 2019 Standards recommend the use of Global Lung Initiative (GLI) as default spirometry reference (31), although other options may be provided.

In addition, since subjects undergo periodic spirometry tests in medical surveillance programs, it is important to evaluate such measurements not only relative to normal ranges [based on predicted values and lower limit of normality (LLNs)], but also relative to the subjects' baselines, particularly when lung function values are within the normal range. Many subjects may have FVC and FEV_1 that exceed their predicted values. Such individuals must lose a significant portion of their lung function before their spirometry results fall below the LLNs, and they are identified as abnormal. Longitudinal evaluations of periodic spirometry testing may detect excessive lung function loss due to an exposure or underlying condition earlier than using a single spirometry test for these individuals. The primary measurement used to assess longitudinal change should be the FEV_1, as it is less affected by technical factors than FVC (5).

The National Institute for Occupational Safety and Health (NIOSH) makes available for free the Spirometry Longitudinal Data Analysis (*SPIRO-LA*) Software, an easy-to-use visual and analytical software, designed to assist healthcare providers in monitoring and interpreting longitudinal spirometry data for individuals as well as for a group (32).

Frequency and Duration of Testing

As length of follow-up increases, real decline in pulmonary function becomes easier to distinguish from background measurement variability. The precision of the estimated rate of FEV_1 decline improves with increasing frequency of measurement and duration of follow-up. Because chronic occupational respiratory diseases (such as chronic obstructive pulmonary disease and pneumoconiosis) typically develop over many years, spirometry performed less frequently than annually (e.g., every 2 to 3 years) should be sufficient to monitor the development of such diseases. However, for diseases that can develop more rapidly (such as flavoring-related lung disease or occupational asthma), more frequent follow up at intervals of 6 months to 1 year may be appropriate (5).

Conclusions

The new 2019 Spirometry Standards, due to their extensive re-organization with numerous updates, will certainly affect manufactures of spirometers, operators and performers of the test. Furthermore, due to the ongoing global impact of the COVID-19 pandemic, much attention must be devoted to strict hygienic controls during testing maneuvers. The latest point is relevant in occupational medicine, since there are many differences between the clinical pulmonary function testing laboratory setting and most occupational settings in which operators perform the test. This is the reason why spirometries in occupational settings outside hospitals have been largely stopped. However, in some cases, spirometry cannot be postponed for a long time, especially in the follow-up of patients who recovered from COVID-19 pneumonia, in order to re-evaluate fitness for work and back-to-work performances.

In the hopefully post-peak or post-pandemic phase, occupational health physicians must be prepared to re-start spirometric assessment consider-

ing both new 2019 Standards and post-peak COVID-19 strategies. This strategy could probably involve a better selection of those workers who really might benefit from spirometric tests. As well, manufacturers must therefore concentrate not only on the technical issues indicated in the 2019 spirometry update, but on cleaning procedures for the equipment of each product; more should be done also on air exchange and adequate ventilation policies (24).

What could be the road ahead for spirometry? The pandemic should encourage clinicians to review and improve their physiological diagnostic and surveillance pathways. Furthermore, in the next few years, we will likely see major technological innovations in the field of lung function tests, among those the development of noncontact respiratory monitoring methods. Spirometers with Bluetooth technology could allow distance between worker and operator and imaging-based methods for noncontact spirometry, which does not require a spirometer, are already under development (photoplethysmography, and body movement detections) (33).

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No potential conflict of interest relevant to this article was reported by the authors