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Spirometry: update of the procedure and post pandemic perspectives

Espirometría: actualización del procedimiento y perspectivas pospandemia

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ABSTRACT. Spirometry is the most widely used and standardized respiratory function test. In 2019, the American Thoracic Society and the European Respiratory Society updated the international guidelines for its execution. The COVID-19 pandemic forced the establishment of better biosafety parameters and has renewed interest in respiratory medicine in the world, including physiological evaluation. The present manuscript summarizes these changes incorporating recommendations and suggestions for countries with limited resources.

Keywords: spirometry, lung function, vital capacity, bronchial obstruction.

Abbreviations:

ATS/ERS = American Thoracic Society/European Respiratory

Society.

COVID-19 = disease by coronavirus 2019.

EOFE = end of forced expiration.

EOTV = end of test volume.

F/V = flow/volume.

FET = forced expiration time.

FEV₁ = forced expiratory volume in one second.

FVC = forced vital capacity.

FIVC = forced inspiratory vital capacity.

IC = inspiratory capacity.

RESUMEN. La espirometría es la prueba de función respiratoria más utilizada y estandarizada. En el año 2019, la Sociedad Americana del Tórax y la Sociedad Respiratoria Europea actualizaron los lineamientos internacionales para su ejecución. La pandemia de COVID-19 ha obligado a establecer mejores parámetros de bioseguridad y ha renovado el interés por la medicina respiratoria en el mundo, incluyendo la evaluación funcional. El presente manuscrito es una propuesta de procedimiento de espirometría ajustado a los cambios e incorpora recomendaciones y sugerencias para países con recursos limitados.

Palabras clave: espirometría, función pulmonar, capacidad vital, obstrucción bronquial.

PEF = peak expiratory flow.

RV = residual volume.

SVC = slow vital capacity.

TLC = total lung capacity.

 $V/T = volume/\overline{time}$.

INTRODUCTION

Forced spirometry is a respiratory function test that assesses components of lung mechanics. It measures the maximum

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volume of air that an individual can forcibly inhale and exhale as a function of time. 1-3

The main variables measured in forced spirometry are: forced vital capacity (FVC), which is the maximum volume of air, measured in litres, that can be exhaled through the mouth with maximum effort after a full inspiration; and forced expiratory volume in one second (FEV₁), which is the volume of air exhaled during the first second of the FVC manoeuvre.¹⁻³

The FEV₁/FVC ratio, expressed as a percentage of the absolute value, is the defining variable for obstruction, as it represents a disproportionate reduction in the maximum FEV₁ of a forced manoeuvre relative to the total volume that a subject can exhale during the FVC manoeuvre. Therefore, a decreased FEV₁/FVC ratio implies airflow limitation, i.e. airway obstruction during exhalation.²

Other spirometric variables briefly addressed in this paper are FEV_{0.5} and FEV_{0.75}, which represent the forced expiratory volume in the specified fraction of a second,^{1,4} as well as the slow vital capacity (SVC) which is the maximum volume of air measured in litres, that can be exhaled through the mouth in a relaxed manner after a full inspiration.¹

This document aims to adjust the spirometry procedure according to the new recommendations published in the 2019 ATS/ERS standard for forced spirometry,¹ as well as the challenges and protocols assumed in its execution in the wake of the COVID-19 pandemic.⁵

INDICATIONS

Spirometry is a fundamental test in respiratory assessment.¹ Indications are shown in *Table 1*, updated according to current evidence on the usefulness of the test in multiple settings.

CONTRAINDICATIONS¹

The FVC manoeuvre directly increases intrathoracic pressure and indirectly increases intra-abdominal and intracranial pressure, and physical exertion can increase myocardial demand. Therefore, the potential risks when performing forced spirometry are due to the impact of these changes on thoracic organs, abdominal, venous return and arterial pressure. The international standard for spirometry¹ states that there are no absolute contraindications for performing forced spirometry and that its performance will depend on the risk-benefit of performing the test.

Patients with contraindications should ideally be evaluated in a pulmonary function laboratory by expert personnel. Slow spirometry may sometimes be performed to assess the subject's vital capacity, although the result is not interchangeable. It is also important that the patient is cooperative and follows instructions in order to avoid

submaximal manoeuvres. The appearance of pain, presyncope or discomfort during the test is a criterion for suspension of the test.

Contraindications, all relative, are shown in Table 2.

MATERIAL RESOURCES

Spirometer

A device that records physiological ventilatory volumes, in the vital capacity range, as well as the flow generated by them through a sensor.²⁷

ATS/ERS 2019¹ states that this equipment must meet the minimum requirements of the latest update to ISO: 26782,²⁷ which are summarised below:

- 1. Measuring range from 0 to 8 litres, under BTPS (Body Temperature and Pressure and Saturated) conditions.
- 2. Maximum permissible error in volume measurement of \pm 3% or 0.050 L (whichever is greater).
- 3. Minimum expiratory time recording of 15 seconds.
- 4. Real-time graphs with a ratio for the F/V (flow/volume) graph of 2 L/s: 1 L and for the V/T (volume/time) graph of 1 L: 1 s.
- 5. Recording of the extrapolated volume as well as the volume at the end of the forced exhalation (to identify start and end criteria).
- 6. Impedance of the equipment, with all its accessories, less than 0.15 kPa/(L/s) with flow rates up to 14 L/s.
- 7. Have a weather station for temperature measurement, which must have an accuracy of ± 1 °C to properly calculate the BTPS correction factor; in case of not having a weather station, the calculation of the correction factor to BTPS units will have to be done manually.
- 8. Appropriate reference equations for the population.³
- Real-time display of F/V and V/T graphs at the time of manoeuvres.¹
- 10. The report generated should have both F/V and V/T graphs for each of the manoeuvres performed; a volume scale \geq 10 mm/L and a time scale \geq 20 mm/s is recommended.³

Volumetric spirometers have fallen into disuse and flow spirometers, which measure air displacement velocity and calculate volume by integration, now predominate. These spirometers are portable, easy to clean, and some use disposable sensors, reducing the risk of cross-contamination; features that have facilitated the incorporation of spirometry in the office, hospital, laboratory and even the patient's home.

Table 3 summarises the different types of flow spirometers, their advantages and disadvantages, virtually all of which are available in Mexico.

Table 1: Indications for spirometry.

Diagnosis1

In suspected COPD:

• Presence of post-bronchodilator FEV_/FVC < LIN or Z-score with symptoms and risk factors^{6,7}

· In suspected asthma:

- It helps during the diagnostic process to document FEV₁/FVC below LIN, especially if it reverses post-bronchodilator. Also an increase of > 400 mL post-bronchodilator in FEV, or FVC
- Repeated spirometry (or PEF) in occupational settings may suggest occupational asthma that worsens at work and improves outside of work
- o If FEV, increases more than 12% and 200 mL from pre-bronchodilator value or from baseline after four weeks of anti-inflammatory therapy8
- In suspected severe asthma, one of the criteria is the presence of pre-bronchodilator FEV. < 80% pred (or ≤ 1.64 in Z-score)⁹

• In suspicion of other respiratory pathology with one or more of the following data:1

- O Symptoms: dyspnoea, cough, wheezing, stridor
- O Signs: rales, thoracic deformity
- O Abnormal laboratory and laboratory studies: hypoxaemia, hypercapnia, polycythaemia, abnormal chest X-ray

Assessment of pulmonary impact of systemic disease:

- In any patient with suspected ILD
- In any patient with neuromuscular disease and suspected respiratory muscle weakness (SVC may be a better indicator of respiratory muscle weakness than FVC as it is not affected by the coexistence of airflow obstruction)^{10,11}
- Difference > 10% in FVC performed in the sitting-supine position (FVC delta) suggests diaphragmatic weakness; unilateral diaphragmatic paralysis may have delta between 15-25% and bilateral up to 50%¹²

· Screening:

- Not indicated in screening asymptomatic subjects without risk factors^{13,14}
- It is indicated in the intentional search for cases: presence of respiratory symptoms or signs and risk factors (> 35 years and smoking rate > 10 p-a, occupational or occupational exposure to biomass or toxic substances)¹⁵
- Decreased FEV, is a cardiovascular risk factor independent of age, sex and smoking¹⁶

• Preoperative risk assessment:1,17

- Respiratory function tests have not been shown to be superior to anamnesis and physical examination in predicting postoperative pulmonary complications in the absence of symptoms and risk factors
- Perform in suspected lung disease without prior diagnosis and in procedures close to the diaphragm (thoracic or upper abdominal surgery)
- Indispensable before lung resection and transplantation surgery

Follow-up1

· Response to therapeutic interventions in lung disease

• Prognosis of already diagnosed lung disease:1

- In COPD, at least once a year to identify 'rapid decliners' (FEV, drop > 50-90 mL/year)^{7,18}
- In asthma, at the start of treatment, 3 to 6 months after achieving control (better lung function) and periodically⁸
- The presence of FEV₁ < 60% pred and/or a very significant response to BD in asthmatic patients (even if asymptomatic or with few symptoms)
 are risk factors for crises⁸
- o In CF, at the start of treatment and every 3 months to identify the pattern of lung function decline¹⁹
- The presence of persistent FEV1 < 40% pred in patients with CF is a criterion for advanced lung disease²⁰
- In interstitial lung diseases (of any aetiology) at least during the first 2 years of diagnosis, as it identifies progressive fibrosing phenotype: fall in FVC ≥ 10% or fall in FVC between 5 and 10% and worsening of respiratory symptoms and/or extension of fibrosis on HRCT²¹
- In muscular dystrophies; if the patient is still walking and < 12 years old, annual is recommended. If the patient is > 12 years, wheelchair user or has an FVC < 80% pred, every 6 months is recommended (FVC < 40% pred is indication for volume recruitment manoeuvres and assisted cough and FVC < 30% pred for non-invasive mechanical ventilation)²²⁻²⁴

Assessment of functional status during and after an exacerbation of the underlying lung disease:

The presence of FEV, < 60% pred in a patient with an asthma flare-up after 48 hours of inhaler titration is an indication for initiation of OCS⁸

Occupational monitoring of subjects exposed to noxious agents:¹

Recommended on admission and annually thereafter. An excessive fall in FEV₁ identified by any of the following methods: % from baseline (> 15%), limit of longitudinal decline or linear regression suggests further evaluation of the worker¹⁸

• During or after the use of drugs with known pulmonary toxicity:

Patients on chemotherapy regimen (bleomycin, gemcitabine, paclitaxel, platinums, cyclophosphamide, doxorubicin). The presence of a spirometric
pattern suggestive of restriction usually occurs in advanced cases, so it is suggested to perform serial DLCO in conjunction with spirometry²⁵

. Disability assessment¹

- Admission to rehabilitation programmes
- Initial assessment by insurers for risk of respiratory pathology
- o Initial assessment of lung health in physically demanding occupations
- Medico-legal assessments

Continued Table 1: Indications for spirometry.

- Other¹
 - Clinical research
 - o Epidemiological studies
 - o Generation of population reference equations
 - Assessment of health status prior to strenuous physical activity
 - o General routine respiratory assessment

COPD = chronic obstructive pulmonary disease. FEV₁ = forced expiratory volume in the first second. FVC = forced vital capacity. %pred= predicted percentage. SVC = slow vital capacity. p-a = pack year. BD = bronchodilator. CF = cystic fibrosis. HRCT = high-resolution tomography. OCS = oral corticosteroids. DLCO = pulmonary diffusion of carbon monoxide. LLN = lower limit of normal.

Table 2: Relative contraindications to spirometry.1

Due to increased myocardial demand or changes in blood pressure

- · AMI: one week prior*
- · Symptomatic hypotension
- Severe hypertension (MAP > 130 mmHg)²⁶
- · Uncontrolled atrial or ventricular arrhythmia
- · Decompensated heart failure
- Untreated pulmonary hypertension
- · Acute cor pulmonale
- Acute PTE
- · History of cough or exertional syncope

Due to increased intracranial/intraocular pressure

- Cerebral aneurysm
- · Cranial or brain surgery: 4 weeks*
- · Recent cranial contusion with persistent symptoms
- · Eye surgery: one week

For increased intraotic pressure

- Sinus or middle ear surgery: One week*
- · Otic infection: one week*

For increased intrathoracic and intra-abdominal pressure

- Unresolved pneumothorax
- · Thoracic surgery: four weeks*
- · Abdominal surgery: four weeks*
- · Late pregnancy

Infection control

- Confirmed or suspected active respiratory infection (COVID-19, tuberculosis or other)
- Physical conditions predisposing to transmission of infection (active haemoptysis, presence of significant secretions, oral lesions or active oral bleeding)

AMI = acute myocardial infarction. MAP = mean arterial pressure. PTE = pulmonary thromboembolism.

* In acute events, forced spirometry is not recommended.

Other equipment and consumables³

1. Computer and printer (some equipments do not require).

- 2. Scale, stadiometer.
- 3. Stable chair with side armrests. Avoid chairs with wheels to prevent falls.
- 4. Room thermometers with an accuracy of 1 °C and hygrometer for relative humidity measurement.
- Mouthpieces recommended by the manufacturer, diving mouthpieces can be used for those patients who are unable to make a good lip seal.
- 6. Nasal forceps.
- 7. Certified three-litre syringe.

Infection control supplies:

- 1. Access to hand washing and gel-alcohol.
- Disposable in-line filters with > 99% efficiency for filtration of viruses, bacteria and mycobacteria; dead space < 100 mL and resistance less than 1.5 cm H₃O at 6 L/s flow rate.
- 3. N95 respirator with leakage of less than 10% and a filtration efficiency of > 95% at a flow rate of 50 L/min.
- 4. Protective eyewear.
- Natural water should be available, as well as facial tissues to be offered to the patient in case of coughing or secretions.

Bronchodilator consumables:

- 1. Salbutamol in metered dose inhaler (100 mg by atomisation).
- 2. Ipratropium bromide aerosol (20 mg per atomisation).
- 3. Reservoir chamber (spacer) with a recommended volume of at least 300 mL.

QUALITY CONTROL AT THE WORKPLACE (Figure 1)

There are requirements that any laboratory or site, where spirometry is performed, must meet to ensure good practice.

Logbook²

We recommend an auditable quality control report. The log should include the results of calibration

Table 3: Types of flow spirometers. 1,27

Type of spirometer	Principle of action	Advantages	Disadvantages
Pneumotacograph (differential pressure)	Measure the pressure difference generated by passing a laminar fluid through a known resistance, where flow = ∆pressure/resistance The resistance may be a mesh or a tube formed by a set of capillaries; it is usually heated to 37 °C to prevent condensation of water vapour from the exhaled gas	Highly accurate at different flow rates Portable Automated Available with disposable sensors	Requires recalibration during the same day if ambient conditions change significantly Accumulation of secretions or condensation of exhaled vapour changes the resistance and hence the flow measurement Susceptible to resistance contamination if used without a filter. Change in gas composition requires calibration
Electronic turbine	It consists of a helix inside the tube that receives the flow. A light emitting diode (LED) is mounted on one side of the propeller and a photodetector on the other side. Each time the propeller rotates, it interrupts the light from the LED reaching the detector. These pulses are counted and summed to calculate the gas flow	Portable Useful in cardiopulmonary exercise testing (CEPPT) Automated Available with disposable sensors	At high flows, the propeller is subject to distortion At low flows, inertia may lead to misestimation of the flow rate Susceptible to turbine contamination if used without a filter Fragile moving parts with a tendency to accumulate dirt that impedes free rotation of the turbine
Thermistor (or hot-wire thermistor)	It consists of two metal filaments (usually platinum) heated by an electric current. The flow of gas through the filaments causes them to cool. In one filament, the current increases to maintain a constant temperature; the other filament acts as a reference. The change in current is proportional to the gas flow	Portable No moving parts Measurement not susceptible to ambient temperature and pressure or fluid viscosity Automated	Sensor resistance connected in series, any modification to the components could be erroneously measured as a flow
Pitot tube	Based on the measurement of the fluid pressure at a given point in the pipe and using the relationship between the pressure and the area the fluid passes through, the fluid flow can be calculated		
Ultrasonic	Ultrasound waves travel through membranes on both sides of a tube at an angle to the gas stream. The sound waves speed up or slow down depending on the direction in which the gas is flowing. By measuring the transit time of the ultrasonic waves (which is modified by the passage of the gas) the flow can be accurately measured	Portable Highly accurate Measurement not susceptible to ambient temperature and pressure or fluid viscosity Air exhaled by the subject is not in contact with the sensor Measures molar mass, with several additional applications possible	Piezoelectric material very sensitive to shocks or falls In absence of HEPA filter (high efficiency particle arrester) favours aerolisation High cost sensors

processes, dates of spirometer maintenance (repairs and/or adjustments) and calibration syringe, software/ hardware updates (dates on which procedures were performed and check that reference equations are

included). Logbooks should be under the custody of the responsible technical professional and always available. Each spirometer should have its own physical or electronic logbook.

Evaluation of spirometer accuracy

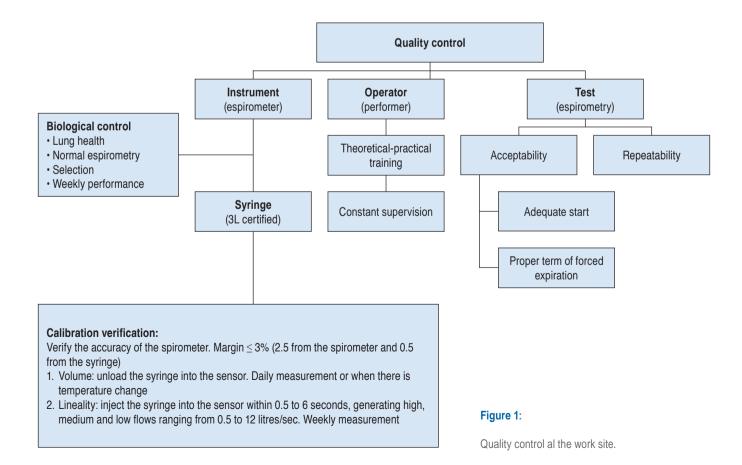
All spirometry equipment must be validated prior to release and subsequently calibrated or verified (before manoeuvres are performed) to meet accurate flow and volume measurements for consistent clinical decisions. The following is a breakdown of the concepts describing these processes:

Validation: assesses the reproducibility of expiratory manoeuvres using a computerized curve generation system. The spirometer must faithfully reproduce the model curve generated by the computer system. It is not part of standard laboratory procedures; it is performed before spirometers are marketed.²⁸

Calibration: a procedure by which a relationship is established between the volume or flow measured by the sensor and the actual flow or volume of the calibrator (syringe) under Ambient Temperature, atmospheric Pressure, Saturated (ATPS) conditions. It is an electrical gain adjustment manoeuvre of the device.¹ Spirometers whose sensor is affected by gas characteristics (condensation, etc.) such as pneumotachographs should always be calibrated.

Calibration verification: procedure that verifies that the spirometer is within the accuracy limits (± 3%, corresponding to: \pm 2.5% of the equipment and \pm 0.5% of the calibration syringe) under ATPS conditions. If the device fails, the verification must be repeated and the possible causes (leakage at the syringe junction with the spirometer, zero flow error, error in the syringe filling and injection process, or malfunction of the syringe) must be analyzed. If the failure is repeated, the equipment should be sent for recalibration and maintenance. The procedure should be performed daily by discharging the calibration instrument (certified three-litre syringe) through the sensor at least three times, in a flow range between 0.5 to 12 L/s (with injection times between 0.5 to 6 seconds). The final result should yield a volume of 3 L \pm 90 mL (\pm 3%). If spirometry is intended to be performed with filters, then this procedure should also use filters. There are spirometers that are pre-calibrated by the manufacturer and cannot be recalibrated by the spirometer operator, however, it is advisable to carry out the calibration verification process on all equipment (even ultrasonic) and generate the corresponding reports that will be filed in the logbook.1

Biological control: performed with the participation of a healthy pulmonary subject, without risk factors, with normal spirometry; usually a laboratory technician



who has the ability to perform the procedure in a highly repeatable manner. It does not replace the use of the calibration syringe. The subject to be designated as the biological control is given serial spirometry for a specified number of days at the same time, averaging the highest FEV₁ and FVC values.¹ Some machines provide the option of automated calculation of the SDs (standard deviations) within which the measurements obtained are considered to be correct. Subsequently, the subject should perform weekly spirometry to compare the measured value against the maximum expected error.

Standardized calibration instrument¹

Corresponds to a three-litre syringe with an accuracy of \pm 15 mL or \pm 0.5%, with a current certificate. It should be checked according to the manufacturer's recommendations and ideally once a month, looking for possible leaks, performing a manoeuvre that attempts to fill and empty the syringe (at different volumes) with the outlet blocked. Similarly, it should be stored away from moisture or heat. A damaged or knocked syringe is considered potentially out of calibration and should not be used for this procedure.

Procedure conditions^{1-3,28}

- ATPS: ambient temperature, barometric pressure and ambient water vapour saturation. All procedures involving the input and output of volumes from a calibration syringe to the sensor must be performed under these conditions.
- 2. BTPS correction: given that exhaled air is at a body temperature of 37 °C and saturated with a water vapour pressure of 47 mmHg; the partial pressure in the lungs is 760-47 mmHg = 713 mmHg (at sea level). All procedures involving the performance of manoeuvres on subjects must conform to these conditions.
- 3. The work site should ideally meet the following characteristics: temperature between 17 to 35 °C, relative humidity between 30 to 75%. Changes in temperature or humidity during the working day should be recorded in the logbook as this may be a source of variability in spirometry results. In situations where the ambient air temperature changes rapidly > 3 °C in < 30 min, the appropriate correction should be made in the spirometer. Artificially air-conditioned laboratories allow better control of environmental variables.
- 4. Some spirometers have built-in sensors that automatically measure temperature and barometric pressure, but it is recommended that the operator verify the accuracy of these parameters.¹

Ongoing staff training

Staff performing spirometry should maintain competence through regular training to safeguard the quality of results. Lack of ongoing training and infrastructure contribute to lack of knowledge about this test.²⁹ A short course improves competence;³⁰ learning is reinforced by a second training of longer duration and close monitoring.²⁹ It is recommended that staff develop skills to cope with special situations including: non-English language (dialects), hearing or visual impairments, and uncooperative patients.¹

Quality of manoeuvres. Review the relevant section.

Improving patient experience³¹

The European Lung Foundation (ELF) conducted a virtual survey in 2018 in 52 countries among patients who regularly underwent spirometry. Of the 1,760 respondents, only 17% of them rated the test as difficult to perform, the rest rated it as tolerable. The most important suggestions from patients were the following: clear and concise information before, during and after the test (regarding drug cessation, contraindications, etc.), as well as access to and explanation of the results obtained in the context of their pathology.

FORCED SPIROMETRY PROCEDURE WITH BRONCHODILATOR^{1,3}

Recommendations for the patient prior to the test

- No smoking, vaping, or using water pipes at least one hour beforehand.
- 2. No use of drugs that affect consciousness within eight hours before.
- 3. No strenuous exercise one hour before.
- 4. Avoid wearing restrictive chest or abdomen garments.
- 5. If the indication for the test is diagnostic, bronchodilators should be discontinued according to the time of action of each (*Table 4*).

Preparation of equipment prior to testing

- All components (hoses, sensors, connectors, etc.) must be properly disinfected and/or sterilised and assembled according to the manufacturer's instructions.
- 2. Perform calibration or calibration verification.
- 3. The spirometer must be coded to the altitude or barometric pressure and average relative humidity of the site where the study is performed.
- 4. Verify that the spirometry report is properly configured.

Type of bronchodilator	Example	Withdrawal time (hours)
SABA (short-acting beta-agonist)	Salbutamol/phenoterol	4-6
SAMA (short-acting muscarinic antagonist)	Ipratropium bromide	12
LABA (long acting beta-agonist)	Formoterol/salmeterol	24
LAMA (long acting muscarinic antagonist)	Tiotropium bromide/umeclidinium/aclidinium/glycopyrronium bromide	36
Ultra-LABA (ultra long acting beta-agonist)	Indacaterol/vilanterol/olodaterol	36-48

Table 4: Bronchodilator withdrawal time in diagnostic spirometry.1

Staff actions on arrival of the patient

- 1. Introduce yourself to the patient and check that your details are correct (check name and date of birth).
- 2. Review the indications.
- 3. Evaluate the presence of possible contraindications, vital signs and the patient's adherence to the recommendations.
- 4. Enter patient data into the spirometer: full name, date of birth, anthropometric parameters: age in years at the day of testing, sex at birth (patients may provide their gender identity, but should be informed that sex at birth is required as it is a determinant of predicted lung size). It is important to enter, as notes or observations, any additional data that may help in the further interpretation of the study (such as smoking, exposures, history of previous lung disease, etc.).
- 5. Obtain the weight in light clothing, on a precision scale and record it in kilograms in closed units to the nearest 0.5 kg.
- 6. Obtain height with a stadiometer (should be measured without shoes, with feet together, standing as upright as possible, facing forward, with back and heels against the wall or stadiometer.)
- 7. In patients unable to stand or with rib cage deformity, measurement of arm span may be used to estimate standing height; measure the distance between the tips of the middle fingers (wingspan). For Caucasian males: height = arm span/1.03, for African-American males: height = arm span/1.06 and for females height = arm span/1.01. For patients who cannot be measured standing and also do not have an arm, the mid-span can be measured as the distance between the tip of the middle finger and the prominent cervical vertebra. And in patients with significant body posture deformity in whom it is not possible to measure the wingspan linearly, the composite wingspan shall be calculated.
- 8. Place the patient in a seated position, in a chair without wheels and with arm support, with the chest and neck in an upright position. If the test is performed in a different position (e.g. decubitus) it should be recorded.

- 9. Explain to the patient, in simple words, the purpose of the test. The following sentence is recommended: «Spirometry is a blowing test to measure the size of the lungs and to find out whether or not there is obstruction of the bronchial tubes. You are going to blow hard and steady through this mouthpiece several times until you get at least three proper manoeuvres».
- 10. A video or picture can be used to reinforce the explanation. It is not advisable to remove eye or respiratory protection to demonstrate the manoeuvre.

Forced vital capacity (FVC) manoeuvres

Manoeuvres that assess both phases of the respiratory cycle (inspiration and expiration), also known as «closed circuit», are preferred.

The four basic steps of a good manoeuvre are as follows:

- 1. Maximal inspiration to total lung capacity (TLC).
- 2. Explosive, immediate and unhesitant exhalation.
- 3. Continuing exhalation until the end of forced expiration criteria are met. At this point the motivation given by the performer is important.
- 4. Breathe in again until TLC. This closes the inspiratory curve and allows assessment of the forced inspiratory vital capacity (FIVC).

In spirometers that do not record the inspiratory phase, open circuit manoeuvres can be performed by placing the mouthpiece immediately after inspiration (step 1) and removing it after meeting end of forced expiratory criteria (step 3).

Figure 2 outlines the steps of a closed-circuit manoeuvre.

Bronchodilator administration³²

The administration protocol should be recorded in writing in the site's internal procedures manual; it should contain the following elements:

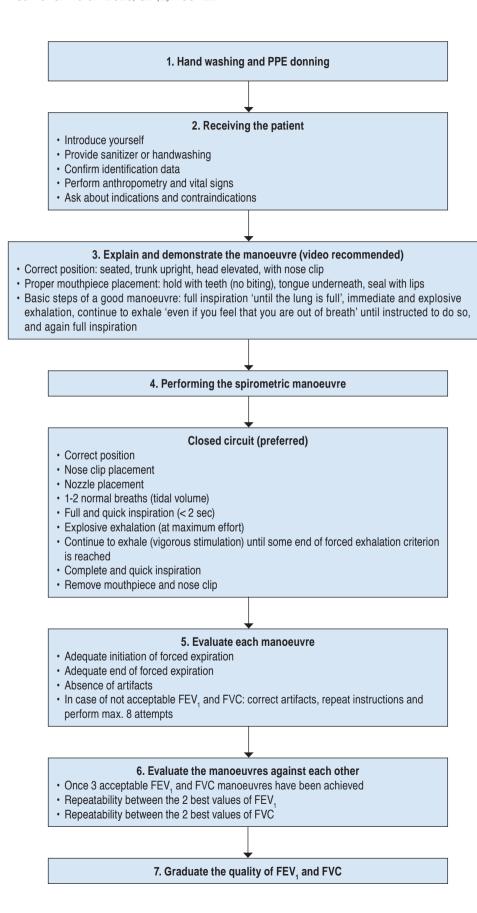
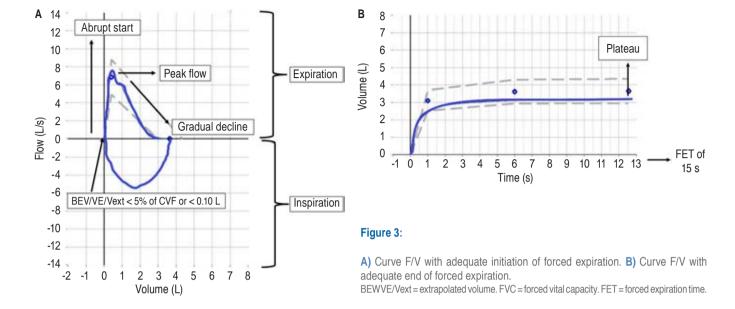


Figure 2:

Spirometric manoeuvre.

PPE = personal protective equipment. FEV₁ = forced expiratory volume in the first second. FVC = forced vital capacity.



- 1. Type of bronchodilator (salbutamol, fenoterol, ipratropium bromide or combinations).
- 2. Dose to be administered in children (salbutamol: $200 \mu g$) and adults (salbutamol: $400 \mu g$, ipratropium bromide: $80 \mu g$).
- 3. Method of administration: metered dose inhaler (MDI) with or without mask, nebuliser. In this regard, MDI with air chamber is recommended; the use of nebulisers should take into account air flow, equipment pressure and not use oxygen while administering the drug.
- 4. Waiting time for post-bronchodilator manoeuvres: when using salbutamol wait at least 15 minutes and in the case of ipratropium bromide at least 30 minutes.

QUALITY OF MANOEUVRES¹

Evaluation of each manoeuvre

At the end of each manoeuvre, it should be assessed for compliance with the following technical acceptability criteria:

1. Adequate onset of forced expiration (*Figure 3A*). An explosive onset, with maximal effort, ensures that we are obtaining the patient's true FEV₄.

The following two indicators must be assessed and met to ensure that the manoeuvre had a correct onset:

- a. The extrapolated volume, which is the amount of gas that is exhaled in a hesitant manner from peak inspiration at time 0, should be < 5% of the FVC or.
- b. The flow/volume (F/V) curve should be triangular in morphology, with steep, vertical rise to peak flow and gradual decline to 0.

2. Adequate end of forced expiration (*Figure 3B*). A proper end of the manoeuvre ensures that the patient's true FVC is obtained.

At least one of the following three indicators must be assessed and met to ensure that the manoeuvre was properly terminated:

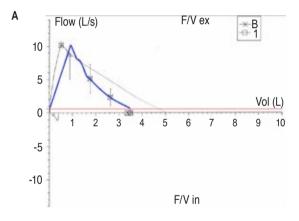
- a. Plateau. This is the best indicator of the end of forced expiration; it refers to an absent increase in volume on the V/T or EOFE curve.
- b. Expiratory time of 15 seconds. This indicator is more likely to be achieved in older adults or in patients with lower airway obstruction. For patient safety, if the plateau has not been reached, but 15 seconds of expiratory time has been reached, the manoeuvre should be terminated.
- c. The subject is unable to continue exhaling. In this case, the FVC of the previous and subsequent manoeuvres shall be assessed to ensure that they are repeatable with respect to each other.

3. Absence of artefacts affecting technical acceptability (Figures 4 to 11).

- a. Baseline errors. Occurs when the operator or patient generates some flow while the equipment is establishing the baseline; affects both FEV₁ and FVC (Figure 4). This artefact is common when spirometry is performed outdoors or near an air conditioning device.
- b. High extrapolated volume. This is generated when the patient takes too long between maximal inspiration and expiratory effort. Its presence renders both FEV₁ and FVC unacceptable and not useful (Figure 5).

- c. Mouthpiece leak or obstruction. Occurs when the patient does not seal the mouthpiece properly with the lips, sticks the tongue in or bites down hard on the mouthpiece. If after verifying proper mouthpiece placement, subsequent manoeuvres still show the «artefact» of obstruction, it is important to rule out true intra- or extrathoracic central airway obstruction. Patients with facial paralysis or edentulous patients without prostheses may require support in sealing (Figures 6 and 7).
- d. Coughing. If it occurs during the first second it affects the FEV₁ result; however, FVC may be usable in such cases (Figure 8).
- e. Glottic closure. The individual pushes instead of exhaling, closing the glottis and suddenly obstructing outflow; if it occurs during the first second it affects both FEV₁ and FVC making the manoeuvre not usable,

- if it occurs after the first second FEV₁ may be usable (Figure 9).
- f. Repeated exhalations. Occurs when the patient reinhales through the nose and exhales again, falsely increasing the FVC of that manoeuvre. The FEV₁ may be usable if the second exhalation occurred after the first second (Figure 10).
- g. Variable efforts. Occurs when the patient does not exhale at maximal effort, which may be suspected in the presence of variable peak flows and non-overlapping traces on the F/V curve (Figure 11).
- h. FIVC-FVC subtraction greater than 0.10 L (100 mL) or 5% of FVC (whichever is higher). If the volume inspired to close the circuit after completion of the forced expiration (FVIC) is much greater than the FVC for that manoeuvre, it means that the patient did not fully inspire at the start of the test, which affects the FVC result.



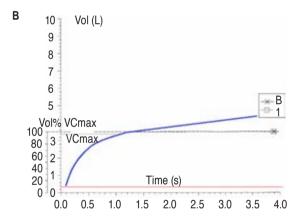
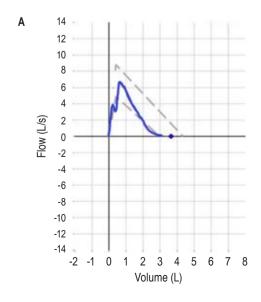
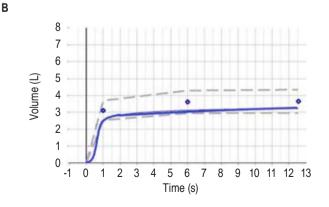


Figure 4: Baseline error. A) The F/V graph starts above flow 0 and does not return to flow 0 at the end of the manoeuvre. B) The V/T graph also does not start at 0 and shows a progressive and infinite increase in volume.

VCmax = maximum vital capacity.





High extrapolated volume. A) The F/V graph presents a false start. B) The V/T graph may present a discrete increase in volume at the beginning of the test that rectifies itself when the patient starts to blow hard.

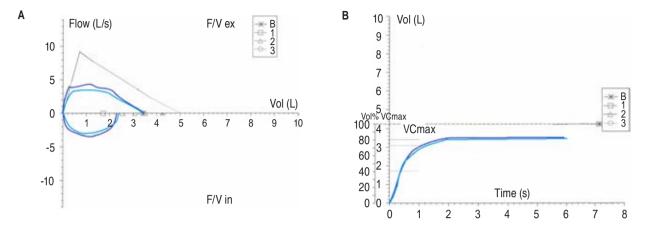


Figure 6: Nozzle obstruction. A) The F/V graph does not have a peak flow despite adequate patient effort. B) The V/T graph discreetly flattened prematurely. VCmax = maximum vital capacity.

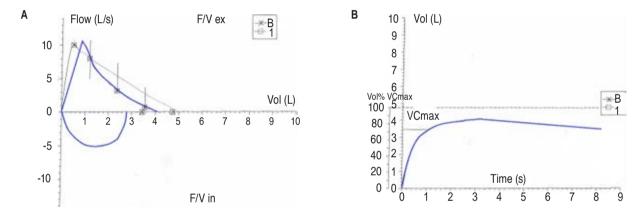


Figure 7: Volume leakage. A) The F/V graph may remain unchanged. B) The V/T graph shows a progressive drop in volume as the subject continues to exhale. VCmax = maximum vital capacity.

ASSESSMENT BETWEEN MANOEUVRES¹

Acceptability implies that each manoeuvre is well executed (from start to finish), while repeatability means that the manoeuvres resemble each other, which is an indicator of measurement consistency. The more consistent a phenomenon is, the lower the probability of error.

Therefore, once three acceptable manoeuvres (both FEV₁ and FVC) have been obtained, repeatability should be assessed under the following criteria: the difference between the two highest FEV₁ values and the two highest FVC values should be \leq 150 mL (maximum \leq 200 mL) in subjects older than six years, and \leq 100 mL or \leq 10% of the highest value in patients younger than six years (Figure 12 and Table 5).

Test quality grades¹

After obtaining three acceptable and two repeatable manoeuvres (in FEV, and FVC) the quality of the test should

be graded (*Table 6*). It is important to note that automated quality does not always match that of the expert observer, so automated algorithms should be used with caution.

Test quality considerations¹

- Acceptability may be achieved in FEV₁ but not in FVC, and vice versa, in the presence of certain artefacts that are difficult to correct for.
- 2. Repeatability is analysed until three acceptable efforts have been completed.
- 3. Eight attempts is a practical limit, but some people, especially those with little testing experience, may get their best manoeuvre after the eighth, especially if they do not show fatigue, in order to get three acceptable ones. Patients who are getting poorer tests or lower measurements with new manoeuvres will generally not benefit from going beyond the eighth manoeuvre.

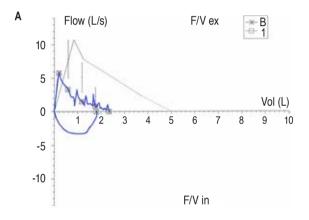
- 4. In case no acceptable manoeuvres in FEV₁ and FVC are obtained, despite our and the patient's efforts, an expert assessor can use the quality score U and issue some interpretation.
- In patients with bronchial hyperresponsiveness, repeated FVC manoeuvres may cause decreased flows.

Reporting the results1-5

It is recommended that it includes sufficient information to assess the quality of the test, as well as a standardised interpretation by an expert. It should include the following components (Figure 12 and Table 5):

- 1. Patient's full name.
- 2. Patient's date of birth.

- 3. Anthropometric parameters (age, gender, ethnicity, weight and height).
- 4. Significant respiratory history.
- 5. Origin of reference values.
- 6. Date of last calibration.
- 7. The values of three acceptable spirometry manoeuvres: FVC, FEV₁ and PEF in units (L or L/s) to two decimal places and the FEV₁/FVC ratio in percent to one decimal place. Depending on the case, FEV₆ and FEV₁/FEV₆ can also be included, and in the case of preschoolers, FEV_{0.5} and FEV_{0.75}, with absolute values and the percentage of the predicted value. It is essential to include the numerical value of the extrapolated volume (BEV, BEV or Vext) and end-expiratory volume (EOTV or EOFE), as well as the expiratory time (FET).
- 8. All three volume-time and flow-volume graphs, both baseline and post-bronchodilator, should be visible.



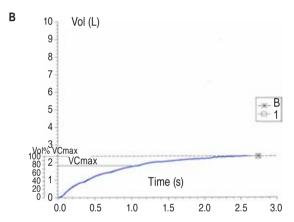


Figure 8: Cough. A) The F/V graph shows sudden fluctuations in flow. B) The V/T graph shows step-like irregularities. VCmax = maximum vital capacity.

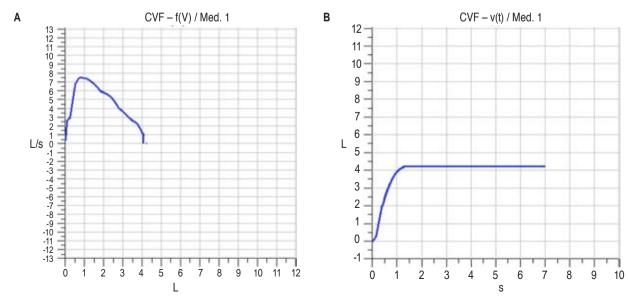


Figure 9: Gothic closure. A) The F/V graph shows a sudden volume drop to 0. B) The V/T graph shows a platou completely flat from the first second.

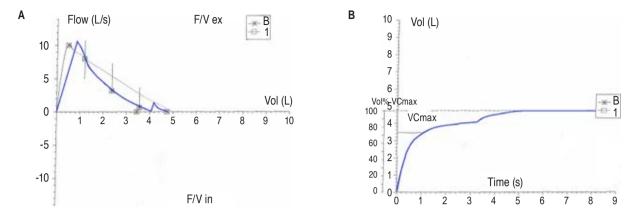


Figure 10: Repeated exhalations. A) The F/V graph shows an additional volume flow curve at the end of the exhalation. B) The V/T graph shows an artificial increase in the forced vital capacity

VCmax = maximum vital capacity.

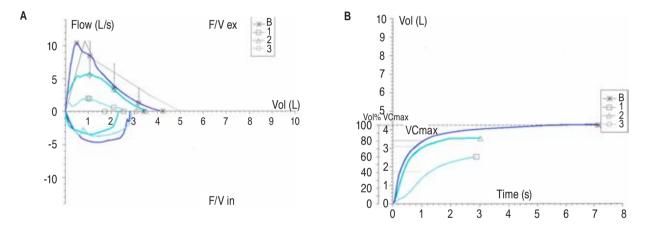


Figure 11: Variable efforts. A) The F/V graph shows no peak flow in two of the manoeuvres, only one is acceptable. B) The V/T graph has a more gradual increase in volume, although the artifact may go unnoticed on the V/T graph.

- 9. The three best values at baseline and the three best values after bronchodilator administration should be displayed. Some outdated spirometers report only the best baseline and best post-bronchodilator values.
- 10. Ideally the change in FEV1 and FVC between the best baseline and best post-bronchodilator test should be reported.
- 11. Column of predicted, lower limit of normal and Z-score.

BIOSAFETY CONSIDERATIONS

Precautions and processes that reduce the risk of personnel exposed to a potentially infectious agent³³ have always been indispensable, but often ignored in healthcare procedures. Potential micro-organisms involved in cross-infection within a pulmonary function laboratory are mainly transmitted by droplets and aerosols; there is also a risk of contact transmission in immunocompromised patients.³⁴

With the emergence of COVID-19, numerous expert consensus proposed limiting the performance of respiratory function tests according to pandemic phase.³⁵⁻³⁷ In a survey of laboratories registered with the American Thoracic Society, only 70% of them continued to perform spirometry in all phases.³⁸ Although there is no similar information from Latin America, the National Institute of Respiratory Diseases in Mexico established biosafety guidelines that ensured the continuity of respiratory physiology services throughout the pandemic.³⁹

Spirometry, like other respiratory function tests, is an aerosol-generating procedure, which requires active breathing manoeuvres in close proximity to the personnel performing the test and may induce coughing. In addition, asymptomatic and pre-symptomatic patients are difficult to detect, regardless of the screening performed.⁴⁰ The pandemic itself has shown us how important it is to assess patients in the respiratory setting, and this includes

spirometry.^{5,38} For full and urgent reactivation of centres performing this test, a hierarchy of risk control must be established, giving priority to processes that protect the collective workforce, without neglecting the surveillance of individual measures.⁴¹

In post-pandemic times, all hygiene and disinfection procedures should be documented in the internal procedures manual. Similarly, the scheduling of each study should consider extending the time between patients, thus avoiding prolonged waiting time and

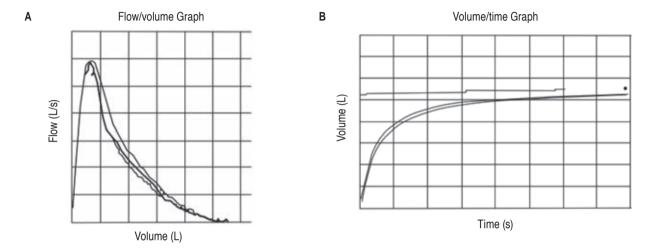


Figure 12: Acceptable single forced spirometry (good onset: F/V graph with abrupt onset, peak flow and gradual decline, extrapolated volume or BEV/Vext less than 0.10 L or 5% of FVC. Good termination of forced exhalation: EOTV or EOFE less than 0.02 L) Repeatable in FVC (4.28-4.16 L = 0.12 L) and FEV, (2.96-2.88 L = 0.8 L).

Table 5: Complete spirometric report.

Forced spirometry Name of the execution site								
Patient's full name	ID			Age (years)				
Sex			Ethnic origin			Height		
Weight (kg)			Date of the test			Predicted (NHANES III)		
Date of last calibration			Initials of the performing technician			Smoking rate/asthma		
				Pre-bronchodilator values				
Parameter	Pred	LIN	Best	Test 1	Test 2	Test 3	% pred	Z-score
FVC (L)	3.73	3.00	4.28	4.28	4.16	4.11	115	1.24
FEV ₁ (L)	2.87	2.25	2.96	2.96	2.88	2.75	103	0.24
FEV ₁ /FVC	0.78	0.69	0.69	0.69	0.69	0.66	88	-1.63
PEF (L/s)	7.80	5.67	6.96	6.62	6.71 6.96			
FET (s)			9.6	9.6	9.3			
FIVC (L)	3.73	3.00	4.00	4.00	3.91	3.74		
EOTV (L)				0.00	0.00	0.00		
BEV or Vext (L)				0.12	0.09	0.08		
FEV.75 (L)			2.62	2.62	2.56	2.42		
FEV.75/FVC (L)			0.61	0.61	0.61	0.58		

NHANES = National Health and Nutrition Examination Survey. Pred = predicted. LIN = lower limit of normal. FVC = forced vital capacity. FEV₁ = forced expiratory volume in the first second. PEF = peak expiratory flow. FET = forced expiratory time. FIVC = forced inspiratory vital capacity. EOTV = end of test volume. BEV or Vext = extrapolated volume. FEV.75 = forced expiratory volume at 0.75/s.

Table 6: Quality grades for FEV, and FVC.1

		ΔFEV_1 and ΔFVC , mL		
Grade	Acceptable manoeuvres	Over 6 years old	Under 6 years of age	Commentary
Α	3	< 150	< 100	Technically highly reliable
В	2	< 150	< 100	Technically reliable
С	2	< 200	< 150	Technically acceptable
D	2	< 250	< 200	Technically with reserve
Е	2 o 1	> 250	> 200	Technically not recommended
U	0 acceptable and 1 useful	N/A	N/A	Rating recommended only for expert assessor
F	0 or 1	N/A	N/A	Technically not recommended

FEV₄ = forced expiratory volume in the first second. FVC = forced vital capacity. N/A = not applicable.

Table 7: Control of occupational hazards when performing spirometry. 5,38

	Engineering control	Administrative control	Personal protective equipment		
Objective	Isolate personnel from exposure	Modify work processes to reduce exposure	Directly protect the exposed worker		
Organizational Impact	Coll	Collective			
Actions	Prioritise implementation by category: Category 1. Urgent or essential (needed for life-threatening treatment) Category 2. Life-limiting (needed to initiate treatments that improve quality of life) Category 3. Routine Category 4. Vulnerable patients Categories 3 and 4 should be reserved for the post-pandemic phase Infrastructure: Ventilation rates of at least 6 air changes/HR HEPA filters with adequate maintenance Negative pressure room for active TB patients Consumables: Disposable mouthpieces (do not reuse) Mandatory use of high efficiency filters	Screening for active respiratory infections: Signs and symptoms questionnaire (re-agendize for active infection data) Immunocompetent do not need negative PCR vs. SARS-CoV-2 30 days after infection Immunocompromised 2 PCRs recommended versus SARS-CoV-2 (-) after illness Organisation of schedule and patient flow: Earmarking first shifts or specific areas for vulnerable patients Physical distance (at least 2 metres) in waiting area Minimise patient exposure time during testing Mandatory mouth cover on patient between manoeuvres Cough or sneeze etiquette when performing the manoeuvre Mandatory handwashing of staff and patient Aerosol break Cleaning and disinfection between patient and patient	Eye protection: Goggles or face shield Respiratory protection: Respirators with more than 95% particulate filtering (FFP2 or N95) Seal test The use of fabric, surgical or other masks is not recommended when testing		

HR = 6 air changes/hour. HEPA = high efficiency particle arrester. PCR = polymerase chain reaction.

overcrowding of subjects, and reducing the risk of infection. *Table 7* summarises the measures according to the international consensus published by the European Respiratory Society.

CONSIDERATIONS IN PAEDIATRICS

With proper training, children as young as two and a half years can perform acceptable spirometry.¹

It is suggested that tidal volume manoeuvres (such as impulse oscillometry) be performed first, followed by forced spirometry, as deep inhalations may change bronchial tone in children with asthma. Children have a high elastic recoil, so these patients may not reach a plateau, in these cases the indicator of adequate EOFE is the repeatability of FVC. Practitioners involved in the performance of pulmonary function testing of young children should be trained to work with this population. *Table 8* summarises some recommendations in this type of patient.^{42,43}

SLOW SPIROMETRY

Spirometry can also be performed in a relaxed or quiet manner, which is referred to as slow spirometry. The slow manoeuvre is comfortable to perform, does not require strenuous physical effort and provides additional information to the forced manoeuvre.

The main measurements obtained from slow spirometry are SVC, which is the slowly exhaled volume from TLC to

residual volume (RV), and inspiratory capacity (IC), which is the slowly inspired volume of air from expiration at tidal volume to maximal inspiration at TLC. It is recommended to be performed before any forced manoeuvre. The manoeuvre consists of the following steps (Table 9):

- 1. Tidal volume breaths (at least three steady ones) and then ask the patient to perform one of the following:
- a) Deep breath in to TLC without hesitation and relaxed exhalation to RV (*Figure 13A*).
- b) Relaxed exhalation to RV and subsequent deep inspiration to TLC (Figure 13B).

The manoeuvres are relaxed and unforced. Peak inspiratory and expiratory levels are usually achieved within the first six seconds, some patients may require more time. The manoeuvre should not be excessively slow, as this may underestimate the SVC. As with forced spirometry, at least three acceptable manoeuvres should be obtained. A

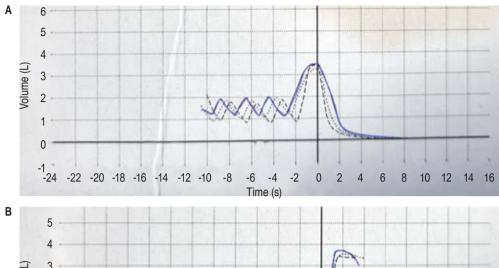
Establish a patient- friendly environment	Greet the child, encourage conversation (compliment the way they are dressed, ask about holidays, school)
Use analogies to explain the test	Instruct the child to play a «blowing game» on the computer Demonstrate the test by blowing into a handkerchief, blowing into a kerchief, blowing into a kettle, or blowing into a spittoon
Maintain correct patient position	Encourage the child to stand upright and hold the flow sensor vertically Use nose clips, but if they are too uncomfortable avoid them
Encourage the patient to perform the manoeuvre properly	Position yourself at the same visual level as the child Be expressive with your body language (change the intonation of your voice, use your hands) Use words the child can understand and simple instructions: «Breathe in», «Breathe out»; «Breathe in until you feel like you're bursting», «Breathe out» Use visual incentives (such as birthday candles)
5. Train your frustration tolerance	Be prepared to try different techniques (open vs. closed manoeuvre) Establish rest periods Offer incentives (stamps, prizes, recognition) Know when to stop. Sometimes it will not be possible to obtain technically acceptable or repeatable spirometry

Table 8: Recommendations for spirometry in paediatric patients.44

Table 9: Slow spirometry manoeuvres.

	Prebronchodilator values							
Parameter	Pred	LIN	Best	Test 1	Test 2	Test 3	% pred	Z Score
VC (L)	3.80	3.09	3.73	3.73	3.64	3.58	98	-0.15
VCex (L)	3.80	3.09	3.70	3.65	3.70	3.69	97	-0.16
VCin (L)	3.80	3.09	3.73	3.73	3.64	3.58	98	-0.15
IC (L)			2.86	2.97	2.88	2.75		
VT (L)			1.03	1.02	1.03	1.02		

LIN = lower limit of normal. VC = vital capacity in litres. VCex = expiratory vital capacity in litres. VCin = inspiratory vital capacity in litres. IC = inspiratory capacity. VT = tidal volume.



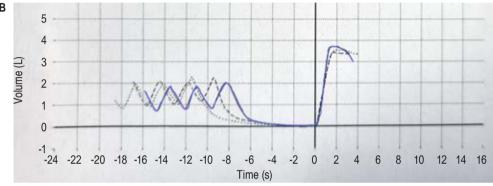


Figure 13:

A) Manoeuvres of slow expiratory vital capacity. **B)** Inspiratory slow vital capacity manoeuvres.

maximum of eight attempts is recommended. The criteria for acceptability are the same as for the forced manoeuvre. Repeatability is assessed by subtracting the values of the two best SVCs, and these should be < 150 mls.

The lack of repeatability in this study is, in most cases, due to incomplete inspiration. For SVC, the highest value of the acceptable manoeuvres should be reported. For IC, the average of the acceptable manoeuvres should be reported. SVC and CI are useful for assessing bronchodilator response, using as criteria for significant response an improvement in 200 mL and 12% in either variable.

FVC and SVC in subjects without airflow obstruction show similar values; however, in obstructed subjects, small airway collapse and air trapping in the forced manoeuvre mean that FVC is lower than SVC.

Limitations of slow spirometry are its lower reproducibility with respect to the forced manoeuvre, less standardisation and fewer reference values available; but, on the other hand, it may be more sensitive in detecting airflow obstruction.

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