Position statement for adult and paediatric spirometry in South Africa: 2022 update

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Spirometry is required as part of the comprehensive evaluation of both adult and paediatric individuals with suspected or confirmed respiratory diseases and occupational assessments. It is used in the categorisation of impairment, grading of severity, assessment of potential progression and response to interventions. Guidelines for spirometry in South Africa are required to improve the quality, standardisation and usefulness in local respiratory practice. The broad principles of spirometry have remained largely unchanged from previous versions of the South African Spirometry Guidelines; however, minor adjustments have been incorporated from more comprehensive international guidelines, including adoption of the Global Lung Function Initiative 2012 (GLI 2012) spirometry reference equations for the South African population.

All equipment should have proof of validation regarding resolution and consistency of the system. Daily calibration must be performed, and equipment quality control processes adhered to. It is important to have standard operating procedures to ensure consistency and quality and, additionally, strict infection control as highlighted during the COVID-19 pandemic.

Adequate spirometry relies on a competent, trained operator, accurate equipment, standardised operating procedures, quality control and patient co-operation. All manoeuvres must be performed strictly according to guidelines, and strict quality assurance methods should be in place, including acceptability criteria (for any given effort) and repeatability (between efforts).

Results must be categorised and graded according to current guidelines, taking into consideration the indication for the test.

Keywords. Spirometry, lung function, impairment.

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Spirometry is required as part of the comprehensive evaluation of children, adolescents and adults with suspected or confirmed respiratory diseases, including asthma and chronic obstructive pulmonary disease (COPD), as well as for screening in certain contexts.[1] It is useful for the general categorisation as well as grading of impairment, for documenting potential disease progression, as well as to assess response to interventions.[1,2] Spirometry, however, should always be interpreted in conjunction with clinical information and the pre-test probability of disease should influence interpretation. Moreover, incorrect standards and operating procedures significantly reduce the value of spirometry in diagnosis and screening for diseases.[1,2]

Guidelines for spirometry in South Africa (SA) have existed for many years, with the aim of improving the quality, standardisation and usefulness of the test itself.[1,3,4] Although the principles have remained largely unchanged, previous guidelines have been supplanted by comprehensive international guidelines.[2] Interpretation of spirometry is based on reference equations used to define normality derived from data from healthy individuals in the same population. There are limited robust data from large diverse population groups in SA, with the largest healthy dataset suggesting black South Africans may have a best fit to the GLI-Other reference equation.[5,6]

The present statement aims to provide an updated and relevant guideline for the use of spirometry in both adults and children at primary healthcare level in SA.

Basic equipment and definitions

Spirometry

Spirometry involves the measurement of air volumes and airflow rates of the lung that are dependent on the physical properties of the airways, lung parenchyma, pleura and chest wall and respiratory muscle strength.[1,2] Practically all modern commercially available computerised spirometers are flow-type spirometers making use of a flow sensor (pneumotachometer) to derive volumes. They allow for the real-time display of expiratory and inspiratory manoeuvres as flow-volume loops, which allow instant pattern recognition. Standard features of modern spirometers include software for the storage of large data sets and the

ability to express measured values as percentage predicted and *z*-scores, using various reference value sets as a guide. These spirometers generally require greater expertise to operate, calibrate and maintain than the older volume-type spirometers, which measured volume directly and produced volume-time curves, but are smaller and more portable. Spirograms (Fig. 1) are graphic displays produced by spirometers and include volume-time curves (both types of spirometer) and flow-volume curves (newer flow-type spirometers).[1] Modern equipment also automatically superimposes measured spirograms on predicted curves to facilitate interpretation.

Measurements

The minimum measurements that should be produced by basic office spirometers include:

1. Forced vital capacity (FVC): FVC is the maximum volume of gas exhaled from the position of maximal inspiration by means of a rapid, maximally forced expiratory effort, expressed in litres as BTPS (body temperature, pressure, water vapour saturated). BTPS refers to a standardised volume at normal body temperature (37°C) at ambient pressure, saturated with water vapour.
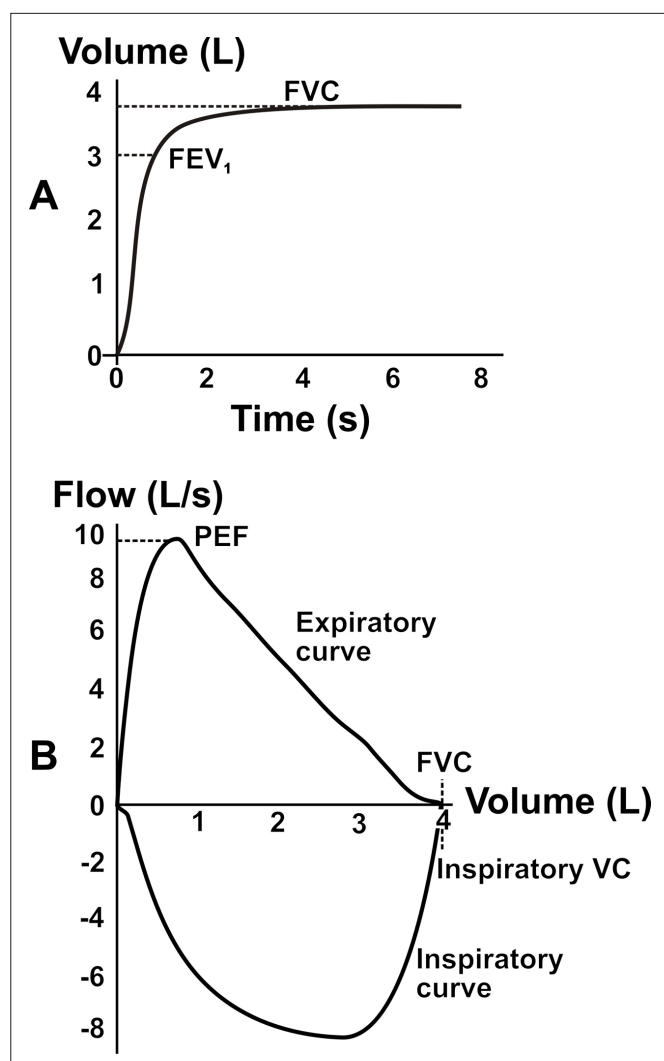

Fig. 1. (A) Volume-time, and (B) flow-volume curves. In the flow-type spirometer, FEV$_1$ is a derived value. It can only be read from the flow-volume graph if a 1 s timer is displayed.

2. Forced expiratory volume in the first second (FEV$_1$): FEV$_1$ is the volume of gas exhaled during the first second of the FVC manoeuvre, expressed in litres (BTPS).
3. FEV$_1$/FVC%: This is the observed FEV$_1$ expressed as the percentage of observed FVC (FEV$_1$/FVC × 100), also called the forced expiratory ratio (FER) or the Tiffeneau-Pinelli index.
4. Peak expiratory flow (PEF): The PEF is the maximum flow generated during a FVC manoeuvre, usually expressed in litres per second (BTPS).

Additional measurements may include:

1. Vital capacity (VC): The 'slow' VC (sometimes referred to as SVC) is the total volume of gas inhaled from the position of maximal expiration or exhaled from the position of maximal inspiration. It is measured with a relaxed/slow breathing manoeuvre either during inspiration or expiration. VC is expressed in litres (BTPS) and may be useful for identifying dynamic small airway collapse in COPD patients (the slow VC will be greater than the FVC).
2. Forced expiratory volume in X second (FEV$_X$): FEV$_X$ is the volume of gas exhaled during the first X second of the FVC manoeuvre, expressed in litres (BTPS), e.g. FEV$_6$ (volume in 6 s) FEV$_{0.5}$ (volume in 0.5 s).
3. Forced expiratory flow (FEF$_{X\%}$): The instantaneous forced expiratory flow rate at the point where X% of the FVC has been expired, e.g. at 25%, 50% and 75% (FEF$_{25\%}$, FEF$_{50\%}$ and FEF$_{75\%}$). These measurements are expressed in litres per second (BTPS).
4. FEF$_{25-75\%}$: Average flow during the middle 50% of an FVC manoeuvre, also sometimes referred to as the maximum mid-expiratory flow (MMEF) expressed in litres per second (BTPS).

Accuracy, repeatability, and reproducibility

Accuracy is the truthfulness or closeness of agreement between the result of a measurement and the true value.[2] **Repeatability** is the closeness of agreement (precision) between the results of successive measurements of the same patient carried out (provided the same methods, instrument, observer and conditions are present), whereas **reproducibility** is viewed as the closeness of agreement of the results of successive measurements of the same item where the measurements are carried out with changed conditions (e.g. methods, observer, instrument, location, conditions of use, or time).[1,2]

Measurement range and equipment resolution

The **measurement range** is the range over which the manufacturer indicates that the device complies with the **equipment resolution**, which is the smallest detectable change in measurement.[3]

Calibration and validation

Calibration is the process whereby the accuracy and repeatability of measurement of a device are tested and corrected using a gold standard, e.g. a calibration syringe with standard volume. **Validation** is the process of establishing and certifying that the device is correctly calibrated.[1,2,]

Indications for spirometry

The indication for spirometry in a particular patient should be unambiguous and should be documented in each case. Current indications for spirometry are summarised in Table 1.

Specifications and technical preparation for spirometry

Validation

All equipment should have proof of validation.[1,2,7] Accuracy depends on the resolution (minimal detectable volume or flow) and linearity (consistency) of the system, from the measuring components to the display and graphical output. The European Respiratory Society (ERS) and American Thoracic Society (ATS) Taskforce for the Standardisation of Lung Function Testing have recommended minimal performance criteria for spirometers and guidelines for validating equipment using waveform-generated calibration syringes are summarised in Tables 2 and 3.[2]

Other recommendations include:

1. A BTPS-correction facility. The volume of exhaled gas is measured outside the body at ambient conditions, designated ATPS (ambient temperature, ambient pressure, saturated with water vapour). These gas measurements are corrected to reflect conditions inside the lung (BTPS). Without this facility, mathematical correction of volumes must be done manually. Depending on the environmental temperature, the BTPS correction factor may be as large as 10%. Ambient temperature, barometric pressure and time of day should therefore be recorded.

Table 1. Indications for spirometry
Diagnostic
Evaluation of abnormal respiratory symptoms and signs (in individuals with suspected obstructive and/or restrictive lung diseases)
Measure to what extent a disease affects the respiratory system
Screening of individuals at risk, e.g. smokers, employees exposed to substances known to cause respiratory disease
Preoperative risk assessment
Assessment of prognosis
Monitoring
Assessment of interventions/treatment action plan
Monitoring the course of chronic lung diseases
Monitoring of patients exposed to injurious agents
Screen for pulmonary toxicity secondary to drugs
Evaluation of impairment
Insurance and disability
Rehabilitation
Assessment for medicolegal purposes
Public health
Epidemiological surveys and derivation of reference equations

Table 2. Selective minimum volume and flow criteria for diagnostic spirometers

Parameter	Volume range (L)	Accuracy* (BTPS)	Repeatability† (BTPS)	Flow range (L/s)	Time (s)	Validation method
FVC	0.5 - 8.0	±3% of reading or ±0.050 L, whichever is greater	±4.5% of reading or ±0.200 L, whichever is greater	0 - 14	30	24 ATS waveforms, 3 L calibration syringe
FEV_1	0.5 - 8.0	±3% of reading or ±0.050 L, whichever is greater	±4.5% of reading or ±0.200 L, whichever is greater	0 - 14	1	24 ATS waveforms
PEF	n/a	±10% of reading or ±0.30 L/s, whichever is greater	±5% of reading or 0.15 L/s, whichever is greater	0 - 14		24 ATS flow waveforms

BTPS = body temperature, pressure, water vapour saturated; ATS = American Thoracic Society; FVC = forced vital capacity; FEV_1 = forced expiratory volume in the first second; PEF = peak expiratory flow; n/a = not applicable.
*Percentage deviation = 100 × (average-standard)/standard.
†Percentage span = 100 (maximum-minimum)/average.

Table 3. Minimum scale for spirograms*

Parameter	Instrument display		Graphical output	
	Required resolution	Scaling	Required resolution	Scaling
Volume	0.050 L	5 mm/L	0.025 L	10 mm/L
Flow	0.200 L/s	2.5 mm/L/s	0.100 L/s	5 mm/L/s
Time	0.2 s	10 mm/s	0.2 s	20 mm/s

*The correct aspect ratio for a flow v. volume display is two units of flow per one unit of volume.

2. A facility to generate real-time spirograms to enhance feedback and subject compliance.
3. Stated source(s) of reference values and the facility to select or enter appropriate values manually.
4. Computer-driven technical quality indicators that meet the latest ATS standards.
5. Printing or electronic facility for record-keeping purposes.
6. Adequate facility to save large numbers of tests and test quality indicators where needed; e.g., for occupational surveillance.

Calibration and equipment quality control

All diagnostic spirometers must be volume-calibrated at least daily using a calibrated syringe with a volume of 3 L (with accuracy of ±0.015 L or ±0.5% for the daily checks) to ensure that they remain accurate during use.[1,2,7,] In some settings (e.g., industrial surveys), the calibration should be performed twice daily. Moreover, calibration should be repeated should the temperature change markedly (>3°C in <30 min). Flow-type spirometers should be calibrated with at least 3 discharges within a range of flows ranging from 0.5 – 12 L/s (with the 3 L syringe this equates to calibration manoeuvres of approximately 6 s and <0.5 s), while performed in calibration mode (to prevent BTPS-correction because room air is injected). Ambient temperature and barometric pressure readings are entered, ideally in the room where testing will be performed (atmospheric variables may be obtained from the local airport or weather bureau or from weather apps). Calibration is complete when the inspiratory and expiratory volumes for the varying flows are within ±3%. Calibration should be done with in-line filters installed. For linearity, a volume calibration check should be performed weekly with a 3 L syringe to deliver 3 constant flows at a low flow, followed by 3 at a mid-range flow and finally 3 at a high flow. The volumes achieved at each of these flows should each meet the accuracy requirement of ±3% (±2.5% for the spirometer itself and ±0.5% for the calibration syringe).[2]

Volume-type spirometers must be evaluated for leaks daily (with 0.3 kPa constant pressure for 1 minute), and quarterly for volume linearity (1 L increments with a calibrating syringe measured over the entire volume range).[2,7]

The calibration syringes(s) should be tested annually with regard to calibration (recalibrated if needed), and also undergo leak testing and general servicing.[2] This should be certified by an independent laboratory, and the quality control and calibration certificates should be stored on site.

Further equipment quality control measures include the installation of software updates (this should be recorded in a logbook) and quarterly calibration of the time clock (by mechanical recorded checks with a stopwatch). In addition to calibration, spirometers must be maintained according to the manufacturer's specifications. This includes the weekly cleaning of pneumotachs, more frequently if there is visible condensate, as they are particularly sensitive to moisture and secretions. It is advisable that the local supplier/manufacturer services spirometers annually.

At a minimum, a calibration and maintenance log and electronic or physical copies of whole spirograms should be kept, so that accuracy and precision of past tests can be verified. Additionally, standard operating procedures should be documented and kept for reference.

Ambient conditions

Ambient temperature, barometric pressure and time of day should be recorded daily. Temperature is a significant variable in spirometry and may be measured directly by a simple thermometer or an internal thermostat (i.e. directly by the equipment). The operator is responsible for confirming the accuracy of temperature measurements, and it is the responsibility of the manufacturer to describe or provide a clear mechanism for checking the accuracy of instrument measurements.[1]

Hygiene and infection control
Rationale

There is a risk of transmitting infections, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), other respiratory viral infections, tuberculosis (TB) and bacterial infections to other test subjects and staff during pulmonary function testing.[1,8] Virtually all the components of the spirometry system have been implicated as an infection control risk, and transmission can occur through both direct and indirect contact with equipment.[1,9] Mouthpieces and the immediate proximal surfaces of valves or tubing are the most likely sources of contamination. The type of test manoeuvre (and specifically whether accompanied by inhalation from the spirometer) has a significant influence on the extent of infection control needed. An expiration-only manoeuvre, without inhalation from the spirometer, reduces the potential for cross-contamination and is the method of choice for mass screening purposes.[1]

Infection control recommendations

Transmission to operators can be prevented by proper hand washing, using barrier devices, e.g. gloves, wearing masks and using appropriate disposable in-line filters for testing. Hands should be washed following direct handling of mouthpieces, tubing, valves or interior spirometer surfaces and always between patients. Operators should be supplied with and wear a surgical mask during the test procedure and gloves when they have open wounds or lesions on the hands, particularly when handling contaminated equipment. N95 masks should be supplied and worn during high-risk testing (e.g. testing during viral pandemics), and the South African Thoracic Society's position statement and practical guide to the use of particulate filtering facepiece respirators should be adhered to.[8]

Cross-contamination should be avoided. Mouthpieces, nose clips and any other equipment that come into direct contact with mucosal surfaces should be disinfected, sterilised or discarded (if disposable) after each use. Equipment surfaces showing condensation from expired air should be disinfected or sterilised before re-use. Manufacturers' recommendations should be strictly adhered to, particularly regarding the choice of sterilising agents, as some equipment may be damaged by chemicals or heat.[1]

Volume-based spirometers that use a closed-circuit technique, should be flushed between subjects with room air at least five times over the entire volume range of the spirometer to ensure clearance of droplet nuclei. The breathing tube and mouthpiece should be decontaminated or changed between patients.[1]

Infection protection control measures are required: in-line disposable filters must be used and replaced after every subject, or the involved parts of the system (spirometer, breathing tubes and resistive element of the pneumotach) must be decontaminated/ sterilised/flushed after each subject. In-line filters are suggested, as re-calibration is necessary every time a system has been dismantled for decontamination.[2]

Special precautions must be taken for patients with known transmissible infections or those with current haemoptysis. In-line filters should be used routinely, even if expiratory manoeuvres are performed exclusively, with sterilisation of contaminated surfaces, or equipment decontaminated after each case. Proper attention should also be paid to environmental control, e.g. ventilation of the room where testing occurs. Practical considerations include testing such cases at the end of the day, to allow overnight decontamination of equipment.

General considerations and preparation

The patient's sex at birth, age, self-identified ethnic group, standing height and weight must be recorded on the day of the test, as these variables are required for reference purposes.[10] Height and weight should be measured with the subject barefoot (feet together), standing upright and eyes looking straight ahead with their back against the wall or stadiometer. Weight is taken wearing only light clothing. The weight and, most importantly, the age and height must be accurate to one decimal place, to avoid prediction bias.[11] The body mass index (kg/m^2) should be calculated. Smoking status and the use of any medication that can influence spirometry should be documented, including the type and dose of drugs and when they were last administered.

Contraindications

The forceful generation of maximal pressures in the thorax with the resultant impact on abdominal and thoracic organs during the performance of spirometry, poses certain risks.[2] There are few absolute contraindications to spirometry, but several relative contraindications to spirometry exist.

Major contraindication criteria: Current respiratory infections in individuals who are not being treated, or treated <2 weeks prior to testing, is a contraindication for assessing permanent impairment/disability, as respiratory infections can temporarily impair lung function.[2] Testing should be postponed in individuals with current haemoptysis (>125 ml per day) to avoid precipitating life-threatening haemoptysis.

Relative contraindication: Lung function testing should not be performed within one week of an acute myocardial infarction, eye surgery or surgery to the sinus or middle ear, or infection of either.[2] Testing should also be postponed in patients within 4 weeks of brain, thoracic or abdominal surgery. Patients who experience syncope with forced and prolonged expiration should not be re-tested.[2]

Subject preparation

Patients should abstain from smoking (within 1 hour) and not perform any vigorous exercise 60 minutes before testing.[2] The specific durations of abstinence prior to testing or bronchodilator responsiveness testing are summarised in Table 4. Clothing that restricts chest and abdominal movement should also be avoided. Patients should be informed of these requirements prior to testing, and deviations should be documented.

Subjects should be relaxed and comfortable before and during testing. For children, an age-appropriate description of what will happen prior to testing and, if possible, providing pictures or videos of the procedure for them to look at in preparation, may improve success, particularly in young children. Tight-fitting clothing should be loosened, and distractions minimised. Well-fitting dentures can be left in place, but loose-fitting dentures are best removed. The use of a nose clip is strongly recommended but using the fingers to pinch the nose closed is acceptable in children and individuals where the nose clip slips off.[1]

It is imperative to use simple instructions to ensure optimal co-operation, which may include real-time visual aids, and incentive graphic software on spirometers is advisable for children. An initial period of training, particularly in children, is essential for better results.[4] Feedback should be given regarding their performance, and patients should be continually encouraged to ensure the best-quality spirometry results possible (including describing potential improvements that can be made).

Subject positioning

Spirometry may be performed either sitting or standing, and the position should be reported.[1,7] The sitting position is the most widely used, primarily because of the small risk of syncope during forced expiration. The chair should have arm rests, but not wheels. Patients should sit in an upright position with the neck extended and the feet planted on the floor directly in front of them.

Execution of tests

FVC and FEV$_1$ test manoeuvres

The operator should follow the summarised procedures (Table 5). The performance of an FVC manoeuvre has four distinct phases: (1) maximal inspiration; (2) rapid, forceful exhalation (a 'blast'); (3) continued complete exhalation for a maximum of 15 s, known as end of forced expiration (EOFE); and (4) inspiration at maximal flow back to maximum lung volume.[2] There are essentially two accepted procedures:

Table 4. Abstinence prior to testing or bronchodilator responsiveness testing	
Activity/product	**Duration**
Prior to testing	
Caffeine products, smoking, vaping, etc.	Within 1 hour
Strenuous exercise	Within 1 hour (patient should rest for at least 15 minutes prior to test)
Prior to testing with bronchodilator responsiveness	
SABA (e.g. salbutamol)	4 - 6 hours
SAMA (e.g. ipratropium bromide)	12 hours
LABA (e.g. formoterol or salmeterol)	24 hours
Ultra-LABA (e.g. indacaterol)	36 hours
LAMA (e.g. tiotropium)	36 - 48 hours

SABA = short-acting β$_2$-agonist; LABA = long-acting β$_2$-agonist; SAMA = short-acting muscarinic antagonist; LAMA = long-acting muscarinic antagonist.

1. Full loop (recommended)

This allows for the recording of inspiration and expiration, and for generating flow-volume loops (on a flow-type spirometer). The subject assumes the correct posture, the nose is occluded, a mouthpiece is inserted (observing that the tongue is not occluding the airway) and the lips sealed tightly around it. The subject is instructed to inhale completely and rapidly while being prompted by the operator with simple phrases such as 'more, more'; if the patient pauses at total lung capacity (TLC), it should be for <1 s; this inspiration should be followed with minimal hesitation by a rapid, forceful (blast) and maximal exhalation until no further air can be expelled (while maintaining an upright posture). The operator should, throughout the procedure, prompt and encourage the subject to perform maximally, while monitoring for the moment a plateau is reached or a forced expiratory time (FET) of 15 s has been reached. Once the forced expiration has been completed, the patient should be asked to inhale as deep and fast as possible with the same encouragement and prompting from the operator to full lung capacity, as with the initial inspiratory manoeuvre. When testing children, the operator should use age-appropriate language, preferably in the first language of the child, be trained in testing children; and the testing environment should be safe and child friendly. The test procedure should be explained in simple terms and well demonstrated.[4] Where possible visual aids should be used prior to testing, children should be encouraged and prompted with basic instructions. Making use of incentive devices, graphics or software can result in acceptable performances.

2. Expiration loop only

This is often employed for mass screening and consists of an FVC test with or without a slow VC test. After the correct posture has been assumed, the nose is occluded. The subject is required to inhale completely and rapidly; this is followed by the individual placing the mouthpiece in the mouth and sealing the lips within 2 s. The patient is then instructed to exhale rapidly, forcefully and maximally, and the mouthpiece can be removed at EOFE.

Quality assurance

Many within-manoeuvre (Table 6) and between-manoeuvre criteria must be satisfied to ensure adequate quality:

1. Start and end of test

The start of forced expiration ('time zero') is determined by the back extrapolation method (Fig. 2), and defines the start for all timed measurements.[2,7] The steepest slope on the volume-time curve is used for manual measurements, whereas the largest slope averaged over an 80 ms period is used for computerised back extrapolation.[1,2] The back extrapolated volume (BEV) is the volume of air that has been exhaled before this 'time zero' and is included in the FEV_1 and FVC

Table 5. Procedures for recording FVC	
Verify spirometer calibration	
Explain the procedure to the subject	
Subject preparation	Enquire about medication use and smoking status
	Measure height and weight without shoes
Infection control	Wash hands or hand sanitiser (operator and patient)
	Disposable filter
Instruct and demonstrate test	Correct positioning and posture
	Complete and rapid inhalation
	Forced, maximal exhalation
Perform manoeuvre	Closed v. open circuit (see text) with nose clip
	Repeat instructions as necessary
	Repeat for a minimum of 3 tests
Verify test quality	Acceptability
	Repeatability
Perform more attempts	Maximum of 8 for adults (up to 10 children <6 years old)

This table is adapted from Graham *et al.*[2]
FVC = forced vital capacity.

Table 6. Within-manoeuvre acceptability criteria for the recording of FVC and FEV_1	
No artefacts	**Coughing during first second of expiration**
	Glottis closure (Valsalva manoeuvre) or hesitation
	Early termination or submaximal effort
	Leakage
	Obstructed mouthpiece
Good starts	Back extrapolated volume <5% of FVC or <0.100 L (whichever is greater)
Exhalation	A plateau of 1 s with volume change <0.025 L (less only if the subject cannot or should not continue)

This table is adapted from Graham *et al.*[2]
FVC = forced vital capacity; FEV_1 = forced expiratory volume in the first second.

measurement. The following criteria are critical to ensure that the FEV_1 comes from a maximal attempt: the hesitation time must be <2 s and the BEV must be <5% of FVC or ≤0.100 L, whichever is greater (the previous minimum 6 s exhalation for EOFE has been updated).[2] Current recommended EOFE criteria also include: (1) subjects cannot exhale to achieve plateau (patients with high elastic recoil or restrictive lung disease); in these cases, a similar FVC in repeated attempts will be a measure of EOFE being reached. A patient should not continue further testing owing to discomfort or the risk of syncope; or (2) the volume-time curve shows no change in volume (<0.025 L for ≥1 s), i.e. reaches a flow plateau. It should be noted that a closure of the glottis will result in early termination of the manoeuvre, resulting in an unacceptable attempt; or (3) if the patient has exhaled for 15 s, the attempt may be terminated, as longer exhalation times rarely change clinical decisions.[2] Manoeuvres not meeting EOFE acceptability criteria will not provide acceptable FVC measures, but an acceptable FEV_1 may be obtained from an attempt with early termination after 1 s. Younger children often struggle to take in a maximal breath before forced expiration. Hence the followed expiration could be inadequate. In simple terms – the more air in, the more air out. The most difficult part of the spirometry manoeuvre for younger children is the complete expiration after forced expiration, as when their lungs feel empty, they do not understand how to keep on applying pressure to their chest and abdomen. Efficient motivation and demonstration must be used. In children <6 years of age, an acceptable $FEV_{0.75}$ can be obtained from an attempt terminating after 0.75 s. It is to be noted that a minimum exhalation time is not required.

2. Acceptability criteria

The within-manoeuvre acceptability criteria for the recording of FVC and FEV_1 are as follows: there must be no artefacts such as coughing within the first second of the exhalation manoeuvre, no obstruction such as the tongue in the mouthpiece/filter, no abrupt/early termination resulting in under-measurement of FVC, leaking by not having an adequate seal of the mouth around the mouthpiece, nor may there be a false/hesitant start (FIVC-FVC should be <0.100 L or 5% of the FVC whichever is greater). Testing with an erroneous zero-flow level can result in the measurements being under- or overestimated. Acceptable curves must satisfy all criteria mentioned, whereas 'usable' curves only need a good start (without hesitation) and to be free of coughing during the first second (Figs 3 - 5). The spirometry system software must provide explicit feedback to the operator with regard to acceptability after each manoeuvre but must have the ability to be overridden by the operator.

3. Repeatability criteria

An adequate test (be it pre-bronchodilator or post-bronchodilator) requires a minimum of three acceptable FVC and FEV_1 measurements – they do not necessarily need to be from the same manoeuvres (Fig. 6).[2] FVC repeatability is achieved when the difference between the largest and the next largest FVC is ≤0.150 L in subjects >6 years of age and ≤0.100 L or 10% of largest FVC, whichever is greater for those ≤6 years old.[2] The criterion for FEV_1 repeatability is the same as for FVC. If these criteria are not met after 3 attempts, additional testing must be performed, up to a maximum of 8 manoeuvres (or until the subject cannot or should not continue or until it is obvious that perseverance will not change the outcome).[9] For children, it may be necessary to make more than 10 attempts at times but, if the
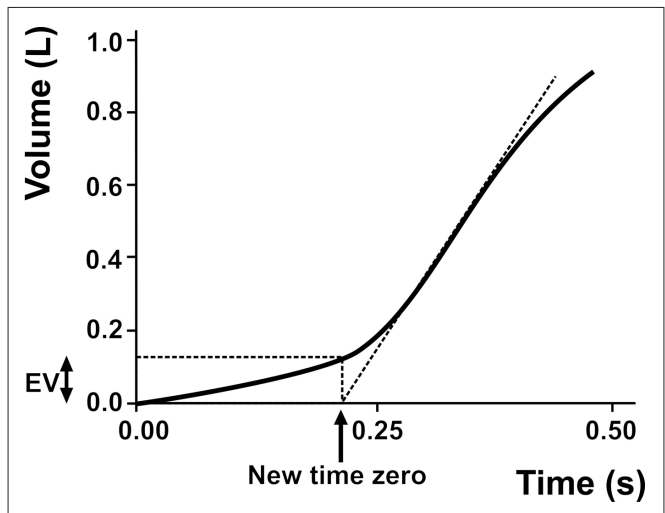

Fig. 2. Expanded version of the early part of a subject's volume-time spirogram, illustrating back extrapolation through the steepest part of the curve, where flow is peak expiratory flow (PEF), to determine the new 'time zero'. Forced vital capacity (FVC) = 4 291 L; back extrapolated volume (EV) = 0.123 L (2.9% FVC), back extrapolation line through PEF.
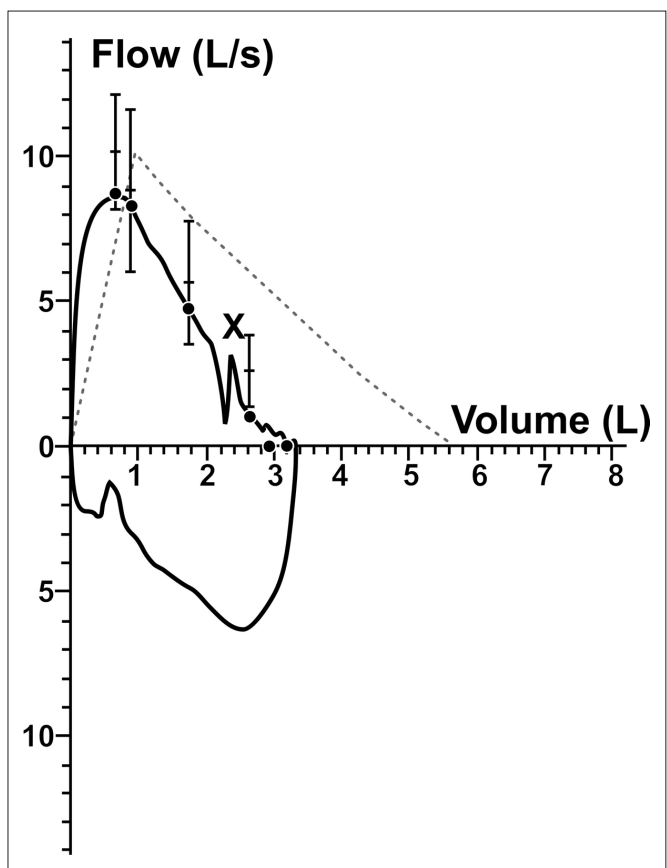

Fig. 3. Flow-volume curve exhibiting cough artefact (X) that can influence observed FVC and FEV_1. Volume-time graphs are better for evaluating end-of-test quality.

child tires or becomes restless, it is advisable to stop and to praise the child for trying – this could result in better attempts in the future. [4] When repeatability is not achieved, results should be labelled as such.
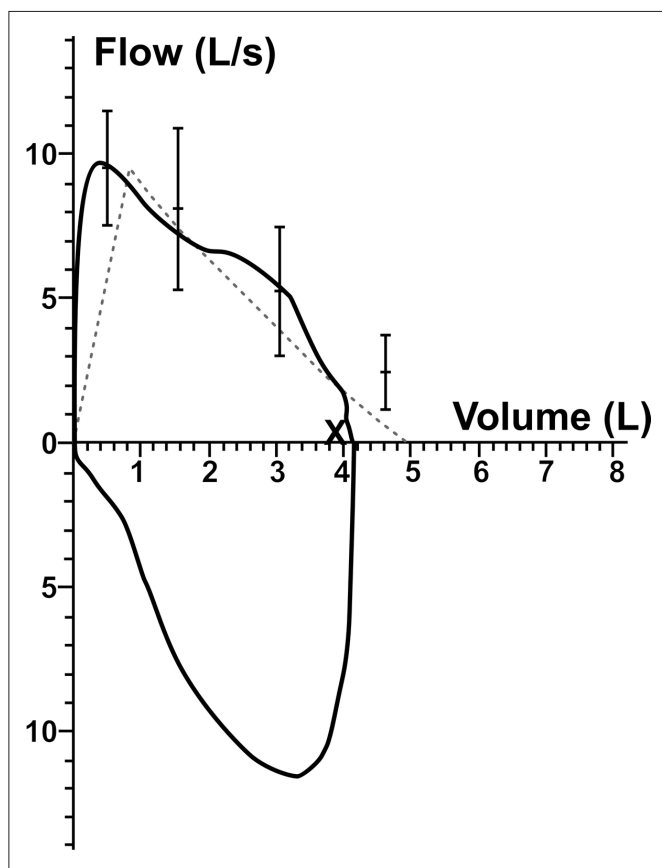
Fig. 4. Flow-volume curves exhibiting glottis closure (X) resulting in premature termination of effort and reduced observed FVC.

Fig. 5. Flow-volume curve with a late peak. Failure to demonstrate reproducibility will confirm these as submaximal efforts.

Test result selection

If there are a minimum of 3 acceptable manoeuvres measured and the FVC and FEV_1 are deemed as repeatable (be it for the pre- or post-bronchodilator test), the largest FVC and largest FEV_1 from these acceptable and repeatable manoeuvres are selected irrespective from which manoeuvre, the FEV_1/FVC ratio is calculated from these 2 'best' parameters. All other indices are determined from the best test which is derived from the test with the largest sum of FVC and FEV_1

Other derived indices

The PEF which is the maximum expiratory flow achieved from the maximal forced expiration, starting without hesitation from the point of maximal inflation, is expressed in L/s.[1] PEF should be achieved within the first 25% of volume expired maximally from a maximal inspiration (most subjects can achieve this within the first 15% of the expired volume).[2] One should note, for comparison, that the PEF measured with the Wright's peak flow meter is in L/minute. The FEF_{25-75} is also known as the maximum mid-expiratory flow. This parameter is dependent on the validity of the FVC measurement and the degree of expiratory effort.[1,7]

Bronchodilator responsiveness test

The term 'reversibility test' has previously been used to denote a significant change which could be inferred to mean that complete elimination of airway obstruction would occur; the term 'bronchodilator responsiveness test' is now the preferred term.[2] The purpose of this test is to determine the degree of improvement of airflow in response to bronchodilator therapy as measured by FVC and FEV_1 changes.[2,7] The
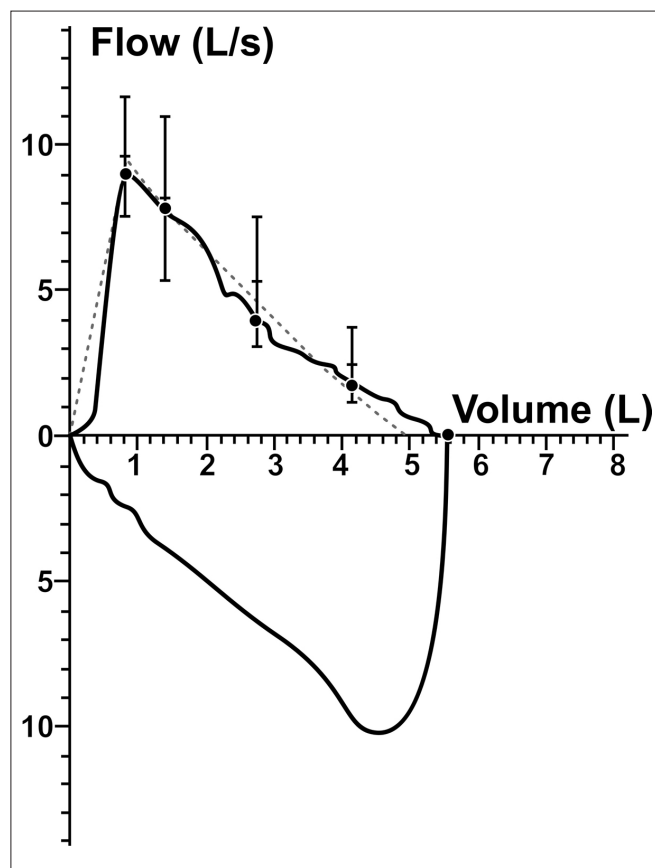
choice of drug, dose and delivery mode is a clinical decision.[1,2,7,9] If the aim of the test is to determine whether the patient's lung function can improve with therapy while being on therapy, the patient is to continue therapy as prescribed. If the aim is to aid in diagnosis using a change in lung function owing to bronchodilator therapy, the patient must abstain from bronchodilators prior to the test for a specified time according to the bronchodilator in use (Table 4).

A standard bronchodilator test is performed as follows:

- The post-bronchodilator test can only be performed if the pre-test was deemed acceptable and repeatable as described previously.
- A short-acting bronchodilator is administered after a gentle expiration to residual volume (RV), or if not possible (for e.g., in young children) a gentle expiration to functional residual capacity (FRC) would be sufficient. A dose of 100 mcg of salbutamol (or equivalent) is gently inhaled in one breath to TLC. The breath is then held for 10 s before exhaling. Three additional doses (total dose 400 μg) are delivered at 30 s intervals. For children, the MDI is administered through a face mask and a spacer for children <6 years and through a spacer with a mouthpiece for children >6 years. Ipratropium bromide (total dose 4 × 40 = 160 μg) can be used as an alternative in adults.
- A waiting period of 10 - 15 minutes follows (30 minutes for ipratropium bromide).
- Three acceptable tests of FEV_1, FVC and PEF (of which 2 are repeatable) must be performed.
- The best post-bronchodilator FEV_1 and FVC are evaluated for improvement compared with the best pre-bronchodilator FEV_1 and
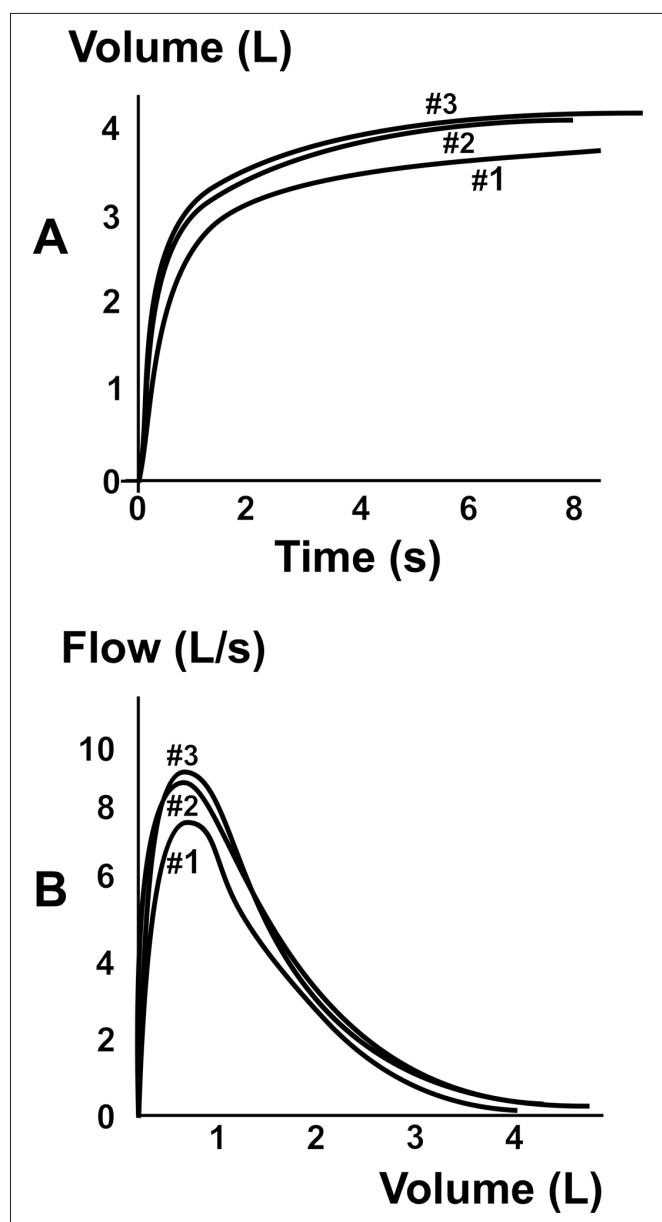
Fig. 6. (A) Volume-time, and (B) flow-volume curves each demonstrating three acceptable FVC trials, only #2 and #3 of which are reproducible.

FVC. The percentage improvement in FEV_1 can be calculated using the formula: (FEV_1 post-BD − FEV_1 pre-BD/FEV_1 pre-BD) × 100 (similarly FEV_1 can be replaced with FVC in the aforementioned formula). A significant bronchodilator response is present if either the FEV_1 or FVC improves by 200 ml and 12%. Recent updated recommendations suggest BDR is calculated as the change in FEV_1 and FVC and is evaluated for improvement as a percentage of the predicted; this value is calculated using the following formula: (post-BD value − pre-BD value× 100)/predicted value.[11]

- Significant bronchodilator responsiveness is present if either the FEV_1 or FVC improves by 200 ml and 12%, or if either FEV_1 or FVC improves by >10% relative to the individual's predicted value for FEV_1 or FVC. Owing to limited data, bronchodilator responsiveness criteria are yet to be validated for children.[11] In adults, there may be complete reversibility (when the post-bronchodilator values recover to at least 80% of predicted) or

partial (when the post-bronchodilator values improve to less than 80% of predicted). Significant bronchodilator responsiveness should always be seen in context. Although common in asthma, it can also be detected in up to 55% of COPD subjects at some point in their disease; similarly, asthmatics with uncontrolled airway inflammation may exhibit persistent airflow limitation and not demonstrate significant bronchodilator responsiveness.[12]

Interpretation and reporting of results
Spirometry reference equations
Observed results should always be compared with an appropriate reference population and expressed as percent observed/predicted.[1,2,4,7] Predicted values for FVC and FEV_1 are calculated from equations based on age, height and sex at birth, as these parameters are the major determinants of lung and airway size in healthy individuals.[1, 2,7,13] Most office spirometers are programmed with many prediction equations derived from the study of patient cohorts. The use of the Global Lung Function Initiative of 2012 (GLI 2012) is currently recommended as the preferred set of predicted equations to be used in SA.[6] The use of inappropriate predicted values can result in a falsely increased rate of abnormal results in clinically normal people.[1] Based on a prospective study of >3 500 healthy SA adults and children of various ethnicities, SATS recommends the GLI 2012 reference equation be used as follows: For SA black and mixed ethnicity populations, the GLI 'other' reference equation (and not 'black') should be used when performing spirometry. The GLI 'white' equation should be used for white South Africans and the GLI 'SE Asian' for people of Indian descent.[5,6]

Historical international guidelines for spirometry and the diagnosis and management of chronic respiratory conditions have used 80% of predicted FVC and FEV_1 as suggested cut-off values, given the ease of calculation and interpretation. This has recently been challenged because of the age dependence of the percentage predicted, e.g. 80% may be more than the lower limit of normal (>LLN) for a 45-year-old adult but would be <LLN for a 12-year-old adolescent. From a scientific perspective, the LLN has superior diagnostic accuracy and should be preferentially used and always used in children and the elderly where the fixed cut-off of 80% predicted FVC and FEV_1 may underestimate disease in the young and overestimate it in the elderly.[1,10,14,15]

Categorisation of spirometric results
When interpreting spirometry, the focus should be on airflow and lung volumes to recognise patterns of altered physiology. These results are used to categorise physiology, but not for making a clinical diagnosis.[11] Interpretation of spirometry should be clear, concise and informative to help understand whether the observed result is normal and, if not, what type of physiological impairment is most likely involved.

The initial assessment is based on a suggested algorithm (Fig. 7) that employs three variables: FEV_1/FVC%, FVC (% predicted) and FEV_1 (% predicted) or the LLN for these parameters. Pattern recognition (see below) can also aid in this assessment. The FEV_1/FVC% ratio of <70% is still advocated by many as indicative of abnormality, despite the fact that that such a crude approach may lead to an underdiagnosis in young patients and an overdiagnosis in elderly patients, which should be avoided.[16] The LLN (i.e. lower than lower 5th percentile), should ideally be used, particularly for screening purposes and in borderline cases.[2]

An obstructive ventilatory defect is defined as a disproportionate reduction in maximal airflow from the lung with respect to the maximal volume that can be displaced from the lung, and per definition the FEV_1/FVC is <LLN.[7] The expiratory limb of the flow-volume loop appears concave (Fig. 8), as flow per volume is reduced. PEF is reduced, as is the $FEF_{25-75\%}$. FVC can be normal or reduced. Obstruction with reduced VC is most often due to air trapping, and the slow VC may be preserved in such cases. Moreover, plethysmography or gas distribution assessment may then be indicated to evaluate the residual volume (RV), total lung capacity (TLC) and other lung-volume parameters. A bronchodilator test should be performed in patients with an obstructive ventilatory defect, unless the indication for the test was purely screening, in which case the patient should be referred to a specialist. The Global Initiative for Obstructive Lung Disease (GOLD) organisation has defined COPD as a post-bronchodilator FEV/FVC <70%; it is now well recognised that there are patients with clinical and imaging features of COPD who exceed this ratio, i.e. >70%.[17,18]

A restrictive ventilatory defect is characterised physiologically by a reduction in TLC as determined by plethysmography or gas distribution assessment (TLC per definition <lower 5th percentile) and can be inferred on spirometry when the $FEV_1/FVC\%$ is normal or high and the FVC is reduced (Fig. 9). Several conditions can reduce FVC, including pulmonary pathology (e.g. interstitial fibrosis), chest wall and pleural disease (e.g. large effusions) and neuromuscular diseases. Flow is often relatively preserved in cases with pulmonary pathology (owing to an increased elastic recoil) but decreased in other causes. Restrictive impairments are often over-diagnosed, predominantly because of poor effort (patient/operator) and inappropriate reference values.[1]

Mixed obstructive-restrictive patterns are sometimes seen, as some diseases (e.g. bronchiectasis) may produce both patterns, and some patients may have dual pathology (e.g. COPD and interstitial pulmonary fibrosis). Both the FEV_1/VC and TLC should be <lower 5th percentile. It may be challenging to categorise a patient solely on spirometry to a mixed pattern, and to distinguish these cases from obstruction with reduced VC. Patients with mixed patterns should therefore be referred to a specialist centre for further investigations.

Variable and fixed large airway obstruction often gives rise to strikingly abnormal flow-volume loops. Fixed obstruction causes a 'hamburger' spirometric pattern, so called because of the shape of the resultant flow-volume loop (Fig. 10). The inspiratory limb is flattened (horizontal) with variable extra thoracic obstruction, whereas the expiratory limb is flattened with variable intrathoracic obstruction.

Grading of severity

Impaired lung function is generally graded to quantify respiratory impairment/disability for medicolegal purposes, and to optimise and standardise treatment.[1] Current guidelines suggest grading both obstructive and restrictive ventilatory impairments solely according to FEV_1, as there is little or no evidence for the use of FVC, VC or even TLC as a parameter of impairment.[19] Pre-bronchodilator FEV_1 values should generally be used when grading abnormal values (Table 7), with the exception of patients with COPD, where post-bronchodilator values are used. Large airway obstruction should not be graded according to the FEV_1.[1] Of note, the grading system reported here is for general spirometry, and differs from certain specific disease entities, e.g. the GOLD statement for COPD.[20]

Although spirometry is often sufficient for the evaluation of respiratory impairment, this is not always the case, and further investigations, e.g. carbon monoxide diffusion capacity (DL_{CO}) and/or exercise testing may be indicated, particularly in patients with clinical evidence of interstitial lung disease or when a disproportionate degree of dyspnoea is present with a relatively preserved FEV_1 and FVC.

Grading of quality of the test session

The standards are designed to help attain the best results possible from a patient. Results are more repeatable when all attempts are performed maximally from maximal lung volumes compared with sub-maximal effort and lung volumes. A suggested grading system (Table 8) has been developed that informs the interpreter about the level of confidence that the spirometry results represent the best that the patient was able to do at the time of the test and the probability that a similar value would be achieved should the test be repeated at a later date.[2]

Reporting

Spirometry reports must contain the following:
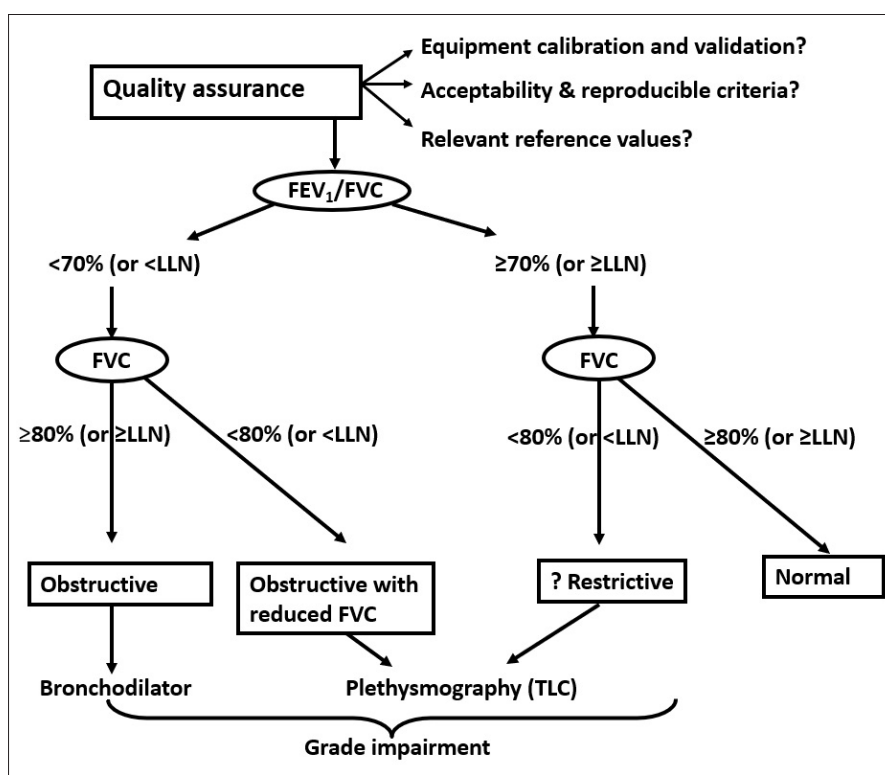1. subject's name
2. date and time of testing

Fig. 7. An algorithm for the categorisation of spirometry. Lower limit of normal (LLN) can be used to replace the percentages of predicted.
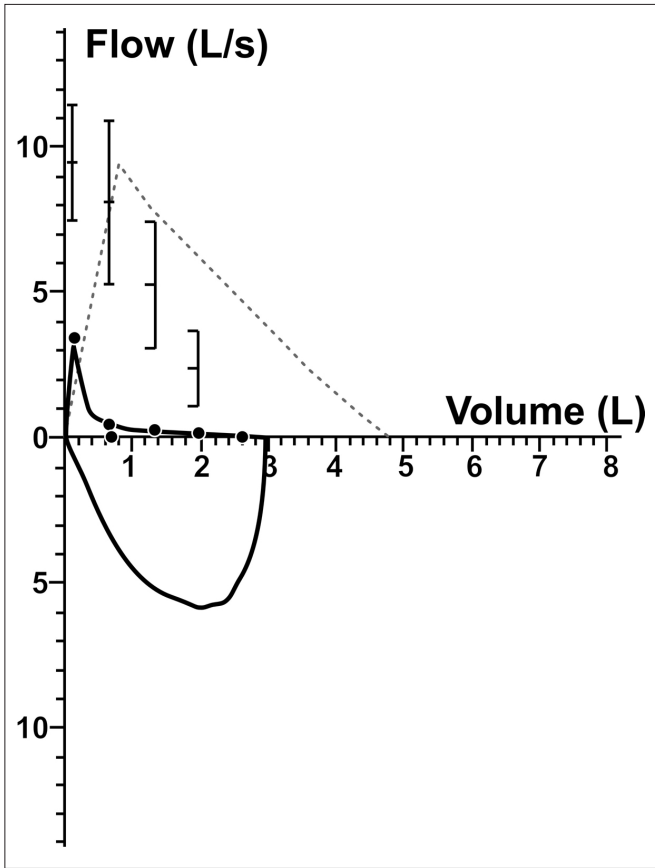
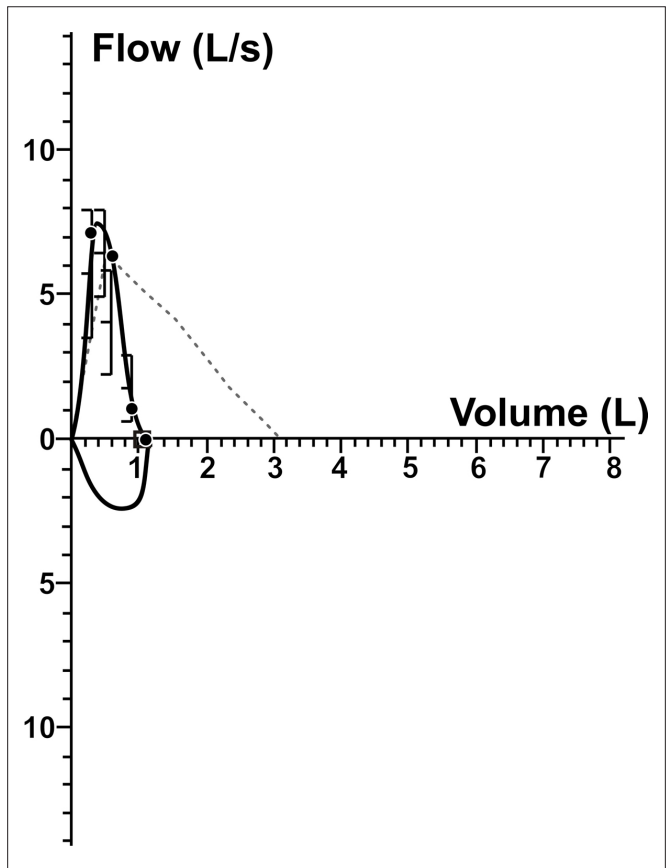Fig. 8. Flow-volume curve exhibiting typical obstruction.

Fig. 9. Flow-volume curve exhibiting a typical restrictive pattern.

Table 7. Severity of any spirometric abnormality based on FEV_1		
Severity	FEV_1 (% predicted)	z-score
Mild	>70	-1.65 to -2.5
Moderate	60 - 69	-2.51 to -4.0
Moderately severe	50 - 59	-
Severe	35 - 49	>4
Very severe	<35	-

This table is adapted from reference 2.
FEV_1 = forced expiratory volume in the first second.

3. subject's age, sex at birth and race
4. subject's height and weight
5. source of reference value (GLI 2012, recommended)
6. latest calibration date
7. numerical values and graphs (flow-volume as well as volume-time) in order to assess acceptability and repeatability
8. basic categorisation.

The ATS recommends including the actual value, LLN, percent of predicted and the z-score (optional) on a spirometry report, if possible.[11] Note that spirometry, as outlined above, is often used to confirm clinical diagnoses and to grade the impairment, but should never be viewed in isolation.[1,2] The final assessment and interpretation of spirometry requires knowledge of medicine and the patient's full clinical details (e.g. to diagnose COPD), and may also require further special investigations (e.g. radiology, DL_{CO} or plethysmography). Pulmonary function technologists and related personnel should therefore reserve the basic
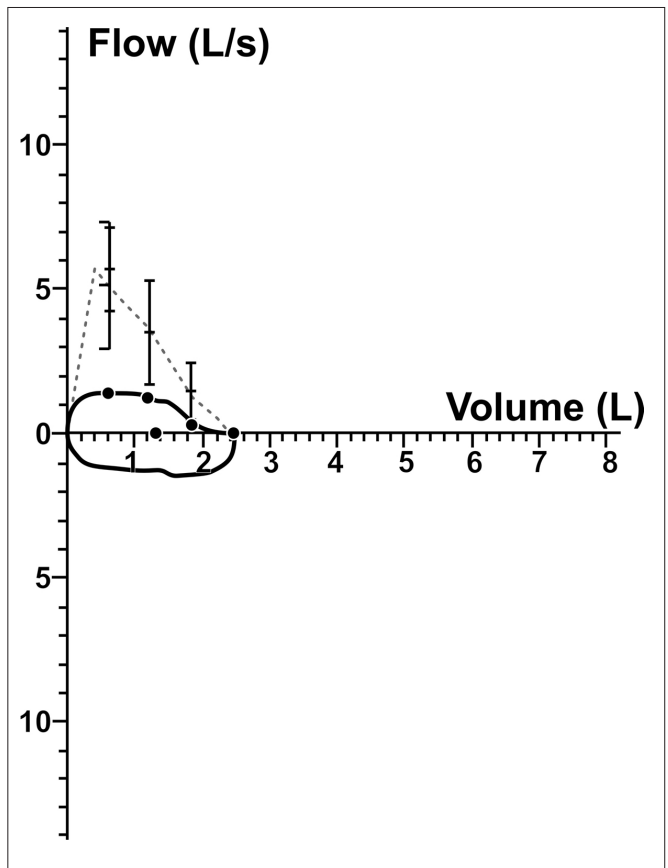

Fig. 10. Example of fixed large airway obstruction.

Table 8. Grading system for FVC and FEV$_1$ (graded separately)

Grade	Number of measurements	Repeatability: Age >6 yrs	Repeatability: Age <6 yrs
A	≥3 acceptable	Within 0.150 L	Within 0.100 L*
B	2 acceptable	Within 0.150 L	Within 0.100 L*
C	≥2 acceptable	Within 0.200 L	Within 0.150 L*
D	≥2 acceptable	Within 0.250 L	Within 0.200 L*
E	≥2 acceptable or 1 acceptable	>0.250L n/a	>0.200 L n/a
U	0 acceptable and ≥1 usable	n/a	n/a
F	0 acceptable and 0 usable	n/a	n/a

FVC = forced vital capacity; FEV$_1$ = forced expiratory volume in the first second; n/a = not applicable.
*Or 10% of the highest value, whichever is greater; this applies to patients ≤6 years only.
The repeatability grade is determined for the set of prebronchodilator and post-bronchodilator manoeuvres separately. The repeatability criteria are applied to the differences between the two largest FVC values, likewise with the FEV$_1$ values. Grade U indicates that only usable but not acceptable measurements were obtained. Although some attempts may be acceptable or usable at grading levels lower than A, the overriding goal of the operator must be always to achieve the best possible testing quality for each patient.
This table is adapted from Graham *et al.*[2]

interpretation to the categorisation of abnormalities and not comment on the presence or absence of a clinically relevant disease process.

Spirometry training and certification
Basic skills
Operators must understand the principles of spirometry summarised in this statement, be able to calibrate the equipment, ensure optimal subject co-operation, provide acceptable repeatability results and categorise common abnormalities (taking relevant reference values into consideration).

Personnel
Pulmonary clinical technologists, general practitioners certified to practise occupational health, specialist physicians and pulmonologists are trained to perform basic spirometry. Pulmonary clinical technologists are competent to perform advanced lung function tests, which are best interpreted by qualified pulmonologists or specialist physicians with an interest in respiratory medicine.

The need to train other healthcare professionals (e.g. nurses) to perform basic spirometry is well recognised, given the paucity of trained personnel.

1. Koegelenberg CFN, Swart F, Irusen EM. Guideline for office spirometry in adults 2012. S Afr Med J 2013;103(1):52-61. https://doi.org/10.7196/SAMJ.6197
2. Graham BL, Steenbruggen I, Barjaktarevic IZ, et al. Standardisation of spirometry 2019 update: An official American Thoracic Society and European Respiratory Society technical statement. Am J Respir Crit Care Med 2019;200(8):E70-E88. https://doi.org/10.1164/rccm.201908-1590ST
3. Van Schalkwyk E, Schults C, Joubert J, White N. Guidelines for office spirometry in adults, 2004. S Afr Med J 2004;94(7):576-587.
4. Masekela R, Gray D, Verwey C, Halkas A, Jeena P. Paediatric spirometry guideline of the South African Thoracic Society: Part 1. S Afr Med J 2013;103(12 Suppl 2):1036-1041. https://doi.org/10.7196/samj.7239
5. Smith SJ, Gray DM, MacGinty RP, et al. Choosing the better Global Lung Initiative 2012 equation in South African population groups. Am J Respir Crit Care Med 2021;202(12):1724-1727. https://doi.org/10.1164/rccm.202005-2085LE
6. Masekela R, Koegelenberg C, Gray D. Guidance to the applicability of the Global Lung Initiative spirometry reference equations for South African populations. S Afr Med J 2020;111(2):97. https://doi.org/10.7196/SAMJ.2021.v111i2.15439
7. Miller MR, Hankinson J, Brusasco V, et al. Standardisation of spirometry. Eur Respir J 2005;26(2):319-338. https://doi.org/10.1183/09031936.05.00034805
8. Dheda K, Charalambous S, Karat AS, et al. A position statement and practical guide to the use of particulate filtering facepiece respirators (N95, FFP2 or equivalent) for South African health workers exposed to respiratory pathogens including *Mycobacterium tuberculosis* and SARS-CoV-2. Afr J Thor Crit Care Med 2021;27(4):177-186. https://doi.org/10.7196/AJTCCM.2021.v27i4.173
9. Miller MR, Crapo R, Hankinson J, et al. General considerations for lung function testing. Eur Respir J 2005;26(1):153-161. https://doi.org/10.1183/09031936.05.00034505
10. Quanjer PH, Stanojevic S, Cole TJ, et al. Multi-ethnic reference values for spirometry for the 3-95-yr age range: The Global Lung Function 2012 equations. Eur Respir J 2012;40(6):1324-1343. https://doi.org/10.1183/09031936.00080312
11. Stanojevic S, Kaminsky DA, Miller M, et al. ERS/ATS technical standard on interpretive strategies for routine lung function tests. Eur Respir J 2022;60(1):2101499. https://doi.org/10.1183/13993003.01499-2021
12. Tashkin DP, Celli B, Decramer M, et al. Bronchodilator responsiveness in patients with COPD. Eur Respir J 2008;31(4):742-750. https://doi.org/10.1183/09031936.00129607
13. Hnizdo E, Churchyard G, Barnes D, Dowdeswell R. Assessment of reliability of lung function. Am J Respir Crit Care Med 2011;160(6):2006-2011. https://doi.org/10.1164/ajrccm.160.6.9902042
14. Levy ML, Quanjer PH, Booker R, Cooper BG, Holmes S, Small IR. Diagnostic spirometry in primary care: Proposed standards for general practice compliant with American Thoracic Society and European Respiratory Society recommendations. Prim Care Respir J 2009;18(3):130-147. https://doi.org/10.4104/pcrj.2009.00054
15. Miller MR, Quanjer PH, Swanney MP, Ruppel G, Enright PL. Interpreting lung function data using 80% predicted and fixed thresholds misclassifies more than 20% of patients. Chest 2011;139(1):52-59. https://doi.org/10.1378/chest.10-0189
16. Quanjer PH, Tammeling G, Cotes J, Pedersen O, Peslin R, Yernault J. Lung volumes and forced ventilatory flows. Report Working Party Standardisation of Lung Function Tests, European Community for Steel and Coal. Official Statement of the European Respiratory Society. Eur Respir J 1993;16(Suppl):5-40.
17. Kole T, vanden Berghe E, Kraft M, et al. Predictors and associations of the persistent airflow limitation phenotype in asthma: A post-hoc analysis of the ATLANTIS study. Lancet Respir Med 2022;S2213-2600(22):00185-0. https://doi.org/10.1016/S2213-2600(22)00185-0
18. Mannino D. Is It time to abandon the postbronchodilator requirement in defining chronic obstructive pulmonary disease? Am J Respir Crit Care Med 2022;206(5):522-524. https://doi.org/10.1164/rccm.202204-0802ED
19. Pellegrino R, Viegi G, Brusasco V, et al. Interpretative strategies for lung function tests. Eur Respir J 2005;26(5):948-968. https://doi.org/10.1183/09031936.05.00035205
20. GOLD Scientific Committee. The Global Initiative for Chronic Obstructive Lung Disease 2022 Report. The Global Initiative for Chronic Obstructive Lung Disease: Published 2022. https://goldcopd.org/wp-content/uploads/2021/12/GOLD-REPORT-2022-v1.1-22Nov2021_WMV.pdf