CLINICAL GUIDELINE

Guideline for Office Spirometry in Adults, 2004

South African Thoracic Society Standards of Spirometry Committee: E M van Schalkwyk, C Schultz, J R Joubert, N W White

Objective. To provide clinical guidelines for office spirometry in South Africa.
Options. More stringent guidelines are required for diagnostic laboratories and research.
Outcomes. To minimise variations in standard practice and improve the quality and usefulness of spirometry in the clinical setting.
Evidence. Recommendations are based on key international publications as well as research publications regarding reference values for South Africans.
Benefits, harm and costs. The medical, social and economic benefits and costs of standardisation of office spirometry in South Africa were considered in the recommendations.
Validation. The document has been reviewed and endorsed by the South African Thoracic Society.
Conclusions. The indications for spirometry must be specific and clear. Spirometry equipment must meet internationally accepted performance standards and carry proof of validation. Equipment must be regularly calibrated and maintained. Individuals performing spirometry must be adequately trained and demonstrate a high level of competence. Subject preparation, testing and quality control of results must be carried out according to published guidelines. Finally, test results must be interpreted according to current diagnostic guidelines, taking into account the purpose of the test, appropriateness of reference values and the clinical evaluation.

S Afr Med J 2004; **94:** 576-587.

1. Abbreviations

ATPS = ambient temperature, ambient pressure, saturated with water vapour; ATS = American Thoracic Society; BTPS = body temperature, ambient pressure, saturated with water vapour; ECSC = European Community for Steel and Coal; ERS = European Respiratory Society; FEV_1 = forced expiratory volume in 1 second; FVC = forced vital capacity; LLN = lower limit of normal; PEF = peak expiratory flow; RSD = residual standard deviation; SATS = South African Thoracic Society; TLC = total lung capacity; VC = vital capacity.

2. Introduction

Spirometry is an essential part of a complete respiratory evaluation, but inadequate standards and variations in standard operating procedures exist that reduce its clinical usefulness.[1] Good quality spirometry necessitates a competent operator, accurate and reliable equipment and a co-operative patient. Furthermore, it involves a series of standard procedures and quality control checks to produce technically satisfactory results. Finally, the results take reference standards into account and are interpreted with consideration of the clinical indications for testing.

Various authorities have published comprehensive guidelines for the standardisation of spirometry.[2-4] More recently, selective South African reference standards have become available for the normal range of forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV_1).[5-10] This statement is prompted by increased utilisation of office spirometry in South Africa and a perceived need for simplified guidelines for use at primary contact level, i.e. in the clinic or practice. Diagnostic and research lung function laboratories will require more comprehensive guidelines than proposed in this document.

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3. Definitions

Spirometry. Spirometry is one of a number of tests to evaluate respiratory function. The basic spirometric procedure involves the measurement of gas volume and rate of airflow during a maximal, forced expiration. The mechanical properties of the airways, lung, pleura, chest wall and respiratory muscles all contribute to these results.

Spirometer. Spirometers operate on one of two principles:

- Volume-type spirometers determine volume directly and have the advantages of low cost and ease of operation. However, data processing and storage capacity may be limited, unless the spirometer contains a microprocessor.
- Flow-type spirometers make use of a flow-sensor (pneumotach) to derive volumes. They are computerised, provide quick reference values, produce flow-volume loops enabling instant pattern recognition and can usually store

large data sets. On the other hand, they require greater expertise to operate, calibrate and maintain.

Spirogram. Spirograms are the graphic displays produced by spirometers. In addition to graphs, they provide the measured values (observed), the reference values (predicted) and the measured values expressed as a percentage of the reference values (% predicted). Volume-type devices generate volume-time curves (Fig. 1a) and flow-type devices generate flow-volume curves (Fig. 1b). Newer flow-type spirometers can produce both types of curve.

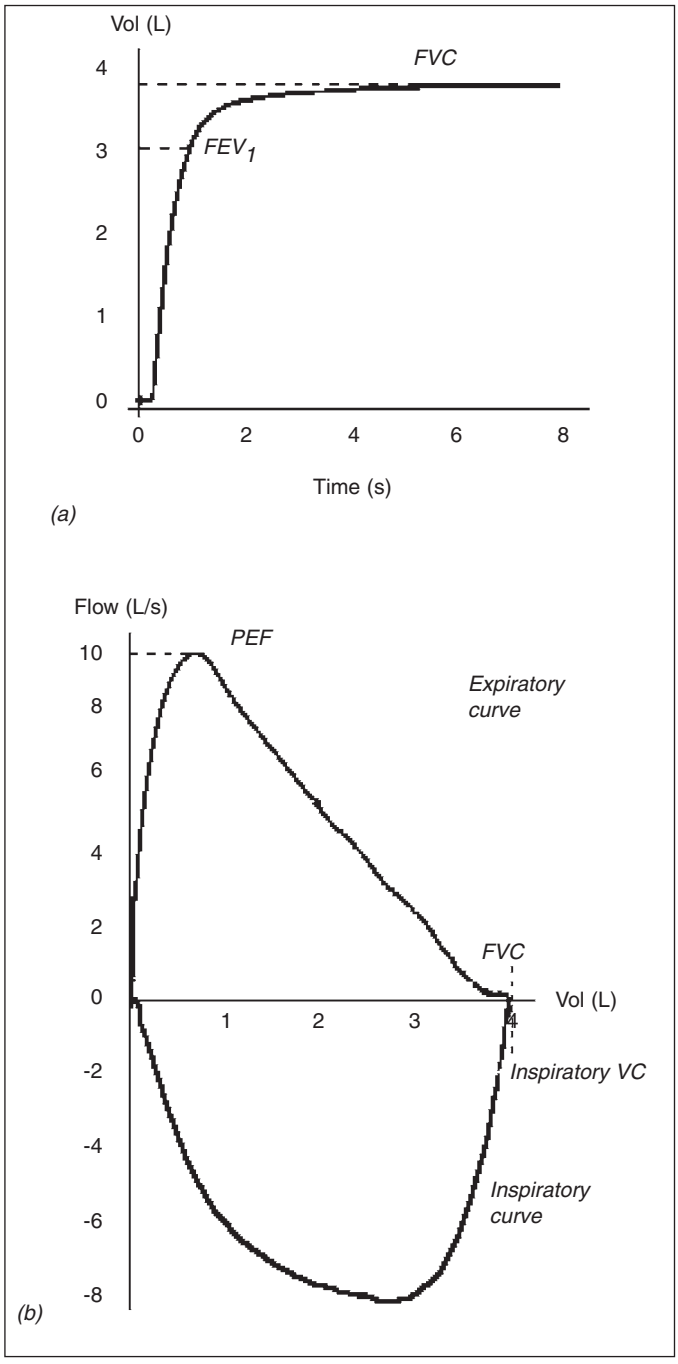

Fig. 1. (a) Volume-time, and (b) flow-volume curves. In the flow-type spirometer FEV_1 is a derived value. It can only be read from the flow-volume graph if a 1-second timer is displayed.

Measurements. Depending on type and level of sophistication, spirometers can produce a range of measurements that may assist in the clinical interpretation of results:

- *Vital capacity (VC)*: VC 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). BTPS refers to a standardised volume at normal body temperature (37°C) at ambient pressure, saturated with water vapour.
- *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 (BTPS).
- *Forced expiratory volume in 1 second (FEV_1)*: FEV_1 is the volume of gas exhaled during the first second of the FVC manoeuvre, expressed in litres (BTPS).
- *FEV_1/FVC%*: FEV_1/FVC% is observed FEV_1 expressed as per cent of observed FVC ($FEV_1/FVC \times 100$).
- *Peak expiratory flow (PEF)*: PEF is the maximum flow generated with a FVC manoeuvre, expressed in litres per second (BTPS).

Measurements of FVC, FEV_1 and FEV_1/FVC% are the minimum required for diagnostic interpretation of results. VC measurements are useful for evaluating dynamic collapse of small airways as found in emphysema.

Calibration. Calibration is the process whereby the accuracy (truthfulness) and precision (repeatability) of a device such as a spirometer are tested and corrected using a gold standard such as a calibration syringe with a standard volume.

Validation. Validation is the process of establishing and certifying the accuracy and precision of a device.

Operator. The term operator refers to the person performing spirometry.

4. Indications for spirometry

Specific and clear indications for spirometry are helpful in the interpretation of results. The most frequent clinical indications for spirometry are listed below:

- To confirm a diagnosis in:
  - Individuals with suspected obstructive or restrictive lung disease.
- To grade respiratory impairment in.
  - Medico-legal cases (e.g. assurance or disability)
  - Individuals on treatment action plans (e.g. COPD)
  - Individuals for lung resection, and individuals for thoracotomy or upper-abdominal surgery if they have chronic respiratory diseases.

- To monitor changes in lung function in:
  - Individuals with chronic respiratory diseases — to evaluate responses to treatment and disease progression.
  - Workers regularly exposed to substances known to cause respiratory diseases.[11]
- To screen for lung disease in:
  - Smokers
  - Individuals with persistent respiratory symptoms, including shortness of breath (dyspnoea), chest tightness, wheezing, coughing, sputum production and chest pain.
  - New employees with potential for exposure to substances known to cause respiratory diseases — to determine baseline lung function.
  - Workers with significant exposure to substances known to cause respiratory diseases.

Spirometry is frequently applied in the occupational environment for surveillance purposes. Its sensitivity and specificity for detecting early disease varies and a screening programme should be tapered to the specific needs of the workplace. For example, early changes of COPD or asbestosis are detectable with spirometry, whereas early changes of silicosis are better detected with chest radiography. For occupational asthma, because of its varying nature, a respiratory symptoms questionnaire is frequently combined with spirometry in screening or surveillance programmes.

5. Specifications for spirometers

5.1 Proof of validation

Spirometers may lack accuracy and precision. Prospective purchasers of equipment should seek its proof of validation. Accuracy depends on the resolution (minimal detectable volume or flow) and linearity (consistency) of the entire system from the measuring components to the recording and display components. The American Thoracic Society (ATS) has published minimal performance criteria for *diagnostic* and *monitoring* spirometers and guidelines for validating equipment using waveform-generated calibration syringes.[2] Selective ATS recommendations for *diagnostic* spirometers are provided in Tables I and II. Table II provides standards for graph output. Manufacturers should follow these guidelines to ensure that spirometers provide accurate data that are comparable between different settings and over time. Commercially available devices for *monitoring* of FEV_1 and PEF have disadvantages for office spirometry because they may be less accurate, usually cannot be calibrated to ensure their performance, and graphical displays may be absent or inadequate for evaluation of test quality.

Other recommendations include:

- The BTPS-correction facility that meets ATS standards: 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 has to be done manually.[2]

Table II. Minimum scale factors for spirograms*

Parameter	Required resolution	Scaling
Volume	0.025 l	10 mm/l
Flow	0.1 l/s	5 mm/l/s
Time	0.2 s	2 cm/s

*For the flow-volume curve exhaled flow is plotted upwards and exhaled volume towards the right in a 2:1 ratio.

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

Parameter	Required range	Accuracy (BTPS)	Flow range (l/s)	Time (s)	Validation method
VC	0.5 - 8 l	± 3% of reading or ± 0.050 l, whichever is greater	0 - 14	30	3 l calibrated syringe
FVC	0.5 - 8 l	± 3% of reading or ± 0.050 l, whichever is greater	0 - 14	15	24 standard waveforms/ 3 l calibrated syringe
FEV_1	0.5 - 8 l	± 3% of reading or ± 0.050 l, whichever is greater	0 - 14	1	24 standard waveforms
PEF		± 10% of reading or ± 0.400 l/s, whichever is greater Precision: ± 5% of reading or ± 0.200 l/s, whichever is greater	0 - 14		26 flow standard waveforms

- Facility to generate real-time spirograms — to enhance feedback and subject compliance.
- Stated source(s) of reference values and facility to select or enter appropriate values manually.
- Computer-driven technical quality indicators that meet ATS standards (computer automatically evaluates test quality based on pre-programmed criteria and gives prompts).
- Printing facility for record-keeping purposes.
- Adequate facility to save large numbers of tests and test quality indicators where needed, for example, for occupational surveillance.
- Availability of after-sales service.

In addition to mechanical validation, spirometers can also be tested in real-life situations involving human subjects.[12]

SATS recommend that independent professional advice from a registered pulmonology training laboratory or the Spirometry Training and Certification Committee of the South African Thoracic Society (SATS) be obtained before a new spirometer is acquired.

5.2 Calibration

All diagnostic spirometers must be volume-calibrated at least daily using a calibrated syringe with a volume of at least 3 l to ensure that they remain accurate during use. During industrial surveys in which a large number of subject manoeuvres are performed, calibration must be checked each morning and at least twice during the day. In circumstances where the temperature may change markedly over the day, for example in field surveys, more frequent temperature corrections are necessary.

Calibration involves the following steps:

1. The spirometer is switched to calibration mode (to prevent BTPS-correction because room air is injected). Room temperature and barometric pressure readings are entered. In the absence of a barometer, barometric pressure readings can be obtained from the local airport or weather bureau.

2. Calibration syringe size is specified. A 3 l syringe is recommended. Currently, the use of 2 l and 1 l syringes is not validated.

3. The calibration syringe is connected to the spirometer and the maximum volume of air injected. Flow-type spirometers are calibrated by injection of the maximum volume from the syringe at least three times, each time at a different speed, to cover a range of flow rates. Calibration is complete when the recorded volumes are within 3% or 50 ml, whichever is the greater, for each flow rate tested. In the event of in-line (antimicrobial) filters being used, calibration should be done with a filter installed. The quality of the filter must be such that the spirometry system still meets ATS standards.

4. Volume-type spirometers are checked for air leaks if the measured volume remains outside the acceptable range. A leak can be detected by applying a slight constant positive pressure with the calibration syringe while the spirometer outlet is occluded. Any volume change greater than 10 ml after 1 minute indicates a leak. Faults are corrected and calibration repeated.

5. Remaining problems are logged and referred to the manufacturer without delay.

The use of biological standards such as, for example, the operator for daily volume calibration (biological calibration) cannot replace the use of a calibration syringe. Lung function testing involves a 'system' consisting of three main components: spirometer, operator and test subject. Each of these can be a source of variation in measurements and syringe calibration is required in order to isolate the device. Biological standards are useful for testing software irregularities such as, for example, inconsistencies in the calculation of predicted values. Also, when they are used in conjunction with a physical standard (calibration syringe), biological standards are useful to test the proficiency of operators.

In addition to daily volume calibration, spirometers must be maintained routinely according to the manufacturer's specifications. This includes the cleaning of pneumotachs at least once a week (more frequently if there is visible condensation), as they are particularly sensitive to moisture and secretions. Other components of the spirometer, for example the time clock, must also be calibrated from time to time. For these and other maintenance functions the manufacturer must routinely check spirometers at least 6 - 12-monthly.

6. Responsibilities of operators

6.1 Skills

Operators must have an understanding of the principles underlying the measurement and equipment operation. They must also be able to ensure optimal subject co-operation, provide acceptable, reproducible results and recognise common abnormalities. Training of pulmonary medical technologists includes this competency and competency to perform advanced lung function tests and laboratory quality assurance. The SATS is in the process of developing a curriculum, training materials and a means of certification of proficiency in performing spirometry for people other than pulmonary medical technologists.

6.2 Quality assurance

A quality assurance programme is critical to ensure a well-functioning spirometry laboratory.[13] This may be difficult to attain in a routine clinical practice. At a minimum, a calibration and maintenance log as well as electronic or hard copies of whole spirograms must be kept so that accuracy and precision of past tests can be verified. Additionally, standard operating procedures should be documented and kept for reference purposes.

6.3 Infection control

Various components of the spirometry system, including mouthpieces, nose clips, pneumotachs, valves and tubing, are potential vehicles for transmission of infection to subjects and staff. Transmission of upper respiratory tract infections, enteric infections and blood-borne infections such as hepatitis and HIV, can potentially occur through direct contact when test subjects have open sores in the mouth, bleeding gums or haemoptysis. Tuberculosis and viral and nosocomial infections can also occur, indirectly, through inhalation of aerosol droplets from the spirometer or surroundings. The type of test manoeuvre determines whether inhalation from the spirometer takes place. This has a major influence on the extent of infection control needed. An expiratory manoeuvre without inhalation from the spirometer reduces the potential for cross-infection dramatically and is the method of choice for mass screening purposes.

Infection control recommendations for expiratory manoeuvres without inhalation from the spirometer:

- Spirometry should be performed in a well-lit and ventilated area.
- Hands must be washed immediately after direct handling of mouthpieces or other potentially contaminated spirometer parts, and between subjects, to avoid operator exposure and cross-contamination. Gloves should be worn for personal protection if there are open cuts or sores on the operator's hands.
- A clean disposable mouthpiece or a disinfected re-usable mouthpiece must be used for every test subject. Any other spirometer part coming into direct contact with mucosal surfaces must be decontaminated/sterilised.
- Spirometers must be cleaned regularly according to the manufacturer's recommendations and the frequency of tests done. Any part with visible condensation from expired air must also be decontaminated before re-use.

Additional infection control recommendations for manoeuvres involving inhalation from the spirometer system or part of the system:

- In-line filters must be used and replaced after each subject, or
- Involved parts of the system (i.e. spirometer, breathing tubes and resistive element of the pneumotach) must be decontaminated/sterilised/flushed after each subject. (Note: re-calibration is necessary every time a system has been dismantled for decontamination.)

Special precautions for patients with haemoptysis or known transmissible infections such as tuberculosis:

- In-line filters must be used routinely (even if expiratory manoeuvres are performed exclusively) with sterilisation of contaminated surfaces only, or
- Equipment must be decontaminated/sterilised/flushed completely after each case. Testing such cases at the end of the day will allow for overnight decontamination of equipment. (Note: indications for spirometry in known active tuberculosis are limited.)

For decontamination/sterilisation procedures, consult the user manual or contact the infection control unit or lung function laboratory at an academic hospital near you.

7. Preparation of subjects

7.1 Exclusion criteria

The main exclusion criterion for spirometry in routine clinical practice is current respiratory infections in individuals for impairment/disability assessment. Respiratory infections can cause temporary lung function impairment and spirometry, if required, should be done only once infections, including tuberculosis, have resolved.

7.2 Personal information

The following information is required for reference purposes (section 9.2) and must be entered into the programme: weight and standing height, age, sex and race. For height and weight measurements the subject should be barefoot and wear only light clothing. It is also useful for interpretation purposes to record the time of last bronchodilator use and smoking status.

7.3 Positioning and preparation

The subject must be made to feel comfortable. Shelter him/her from other subjects to minimise inhibitions or distractions. Loosen tight clothing. Leave well-fitting dentures in, but remove loose-fitting ones. Test the subject sitting upright on a firm chair with his/her chin slightly elevated and neck slightly extended. This posture should be maintained during the forced expiration. Discourage excessive bending at the waist. Use of a nose clip is strongly recommended. Instruct the patient when to insert the mouthpiece, for example, at the end of maximal inspiration. Ensure that the subject does not bite the mouthpiece too hard, that the lips are sealed tightly around it, and that the tongue does not obstruct the mouthpiece in any way.

Ensure maximum subject co-operation. Submaximal efforts are a frequent cause of abnormal results. Explain techniques in simple terms and demonstrate them to the patient. For example, explain that: 'I am going to have you blow into the machine to see how big your lungs are and how fast the air comes out. It does not hurt but requires your co-operation and lots of effort.' Explain and demonstrate the use of a nose clip and mouthpiece. Remind the patient of a few key points. 'Be sure to take as deep a breath as possible, blast out hard and do not stop blowing until I tell you to do so.' Give feedback about the performance, encourage and describe what improvements can be made.

8. Execution of tests

8.1 Test manoeuvres

Test manoeuvres are determined in part by the setting and level of sophistication of the spirometer:

- **Expiratory-only method.** For reasons of ease, cost and infection control this method is recommended for mass screening. It consists of a FVC test with or without a slow VC test. For the FVC test, the test subject is required to inhale maximally before inserting the mouthpiece and starting the test. Expiration must be rapid, forceful and complete, lasting at least 6 seconds. If significant obstruction is demonstrated, proceed with a slow VC test. The slow VC test is preceded by a maximal inspiration, the mouthpiece is inserted and the patient then breathes out in a relaxed fashion and for as long as possible. Allow for up to 15 seconds. Only the VC is recorded. *The rationale for performing a slow VC test is as follows: the slow VC provides additional information on the characteristics of the obstructive defect. A reduction in FVC compared with slow VC suggests dynamic collapse of unsupported airways during forced expiration leading to air trapping. This pattern is typically seen in emphysema.*
- **Inspiratory-expiratory method.** With this method both inspiration and expiration are recorded to generate a flow-volume curve on a flow-type spirometer. Typically, after insertion of the mouthpiece, a period of quiet breathing is followed by a complete expiration, a rapid, forceful and complete inspiration and finally, a rapid, forceful and complete expiration. Some programmes prompt for an expiratory manoeuvre followed by an inspiratory manoeuvre. However, the first method is recommended, because this will reveal air trapping as described in the previous section. Reduced FVC compared with forced, inspiratory VC is suggestive of air trapping.

8.2 Test quality

The final step in ensuring data quality is the evaluation of spirograms for *acceptability* and *reproducibility.*

8.2.1 Acceptability

A technically acceptable FVC trial (Fig. 1) must exhibit the following qualities:

- A 'crisp', unhesitating start.
- PEF of the flow-volume curve achieved within the first 25% of the volume expired from maximum inspiration. (Most individuals are able to produce PEF within the first 15% of the volume expired.)
- A continuous smooth exhalation without artefacts caused by coughing, variable effort, second inhalations or leaks influencing FEV_1 or FVC.
- A complete exhalation (to the point where no more air can be expelled from the lungs), lasting until the volume-time curve has clearly reached a plateau or the flow-volume curve has progressively returned to zero flow.

All technically unsatisfactory trials must be rejected. Common patterns are illustrated in Figs. 2 - 4.

8.2.2 Reproducibility

Suboptimal effort by the test subject is a frequent cause of diminished lung function results. Ensuring reproducibility of test results is a way of verifying that the test subject co-operates fully and provides maximal effort. Reproducibility is defined as two curves in which the difference in FVC and FEV_1, respectively, do not exceed 0.2 l. Reproducibility is usually evident from the spirogram at a glance (Fig. 5). Testing

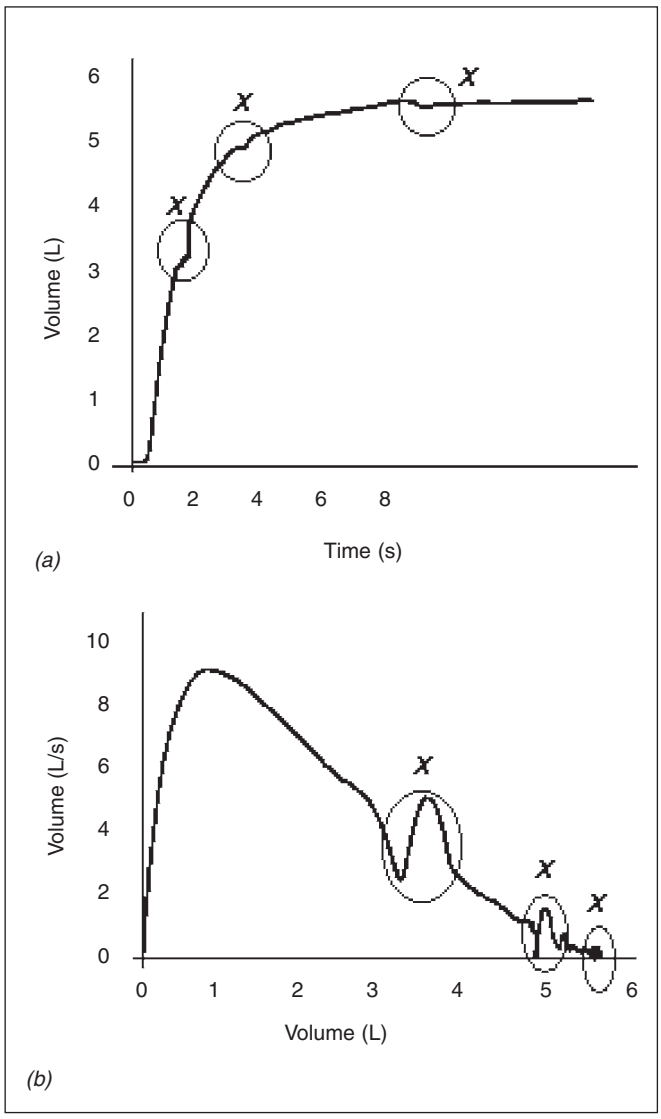

Fig. 2. (a) Volume-time, and (b) flow-volume curves exhibiting cough artefacts (X) that can influence observed FVC and FEV_1. Volume-time graphs are better for evaluating end-of-test quality.

must continue until a minimum of three technically *acceptable* FVC trials have been obtained, at least two of which are *reproducible*. However, no more than eight trials should be performed during a single session, because fatigue induced by repeated FVC trials can lead to reduced results. Subjects with asthma sometimes demonstrate spirometry-induced bronchoconstriction leading to a progressive reduction in lung function with successive trials. This finding will be of interest to the clinician and all acceptable curves should be kept for reporting. Failure to obtain reproducibility after eight trials must be documented, but selection of the best curve may proceed.

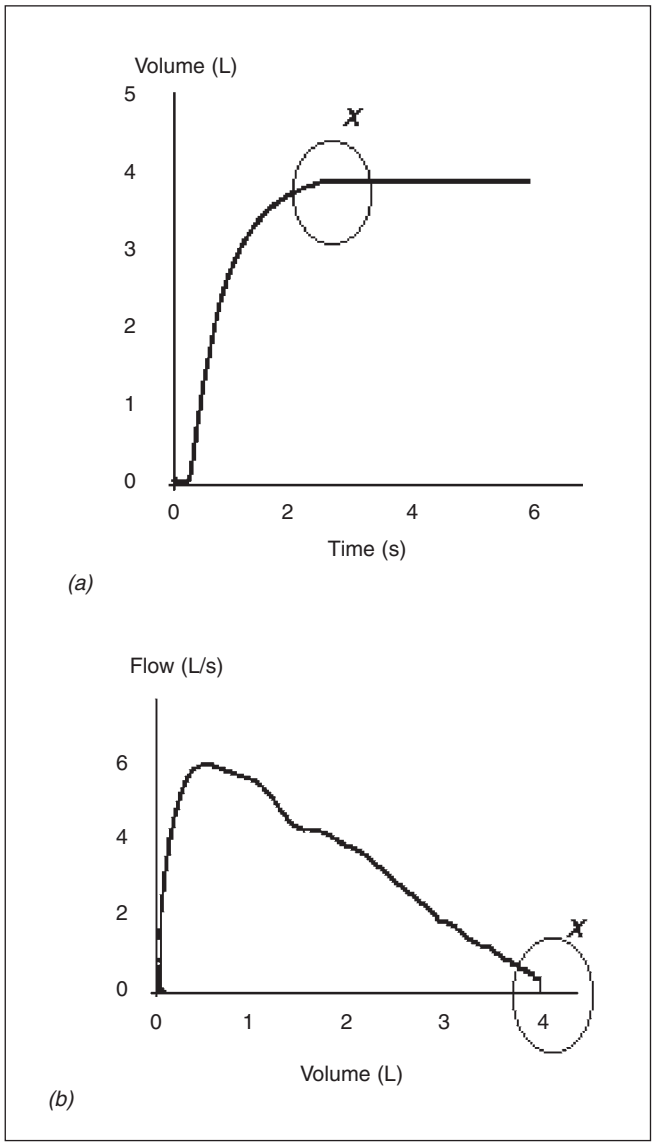

Fig. 3. (a) Volume-time, and (b) flow-volume curves exhibiting glottis closure (X) resulting in premature termination of effort and reduced observed FVC.

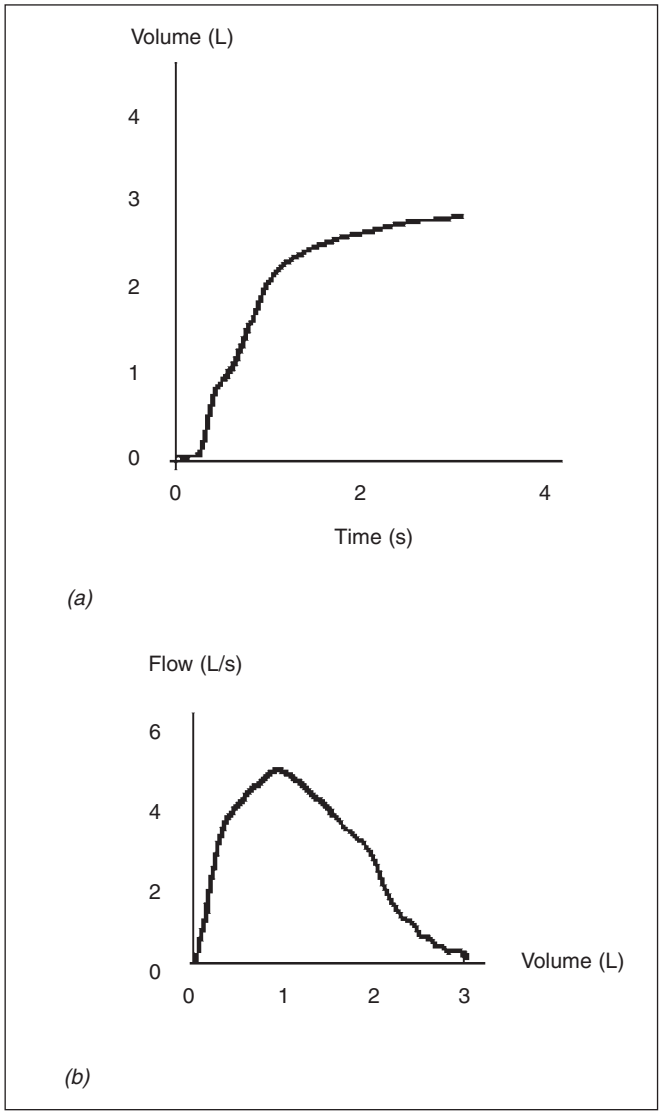

Fig. 4. (a) Volume-time curve exhibiting a slow rise and the end-of-test not reaching a plateau, and (b) flow-volume curve with a late peak flow and an abrupt end-of-test. Failure to demonstrate reproducibility will confirm these as submaximal efforts.

9. Interpretation of results

9.1 Selection of the best test

For diagnostic purposes, the best spirogram must be inspected, i. e. the graph with the largest sum of FVC and FEV_1. For impairment or severity grading the highest values recorded for FVC and FEV_1 must be selected from all acceptable curves, including the post bronchodilator curves, even if they come from separate curves.

9.2 Reference standards

An individual's observed results are evaluated for abnormalities against predicted results derived from a normal

reference population. The comparison is made as per cent observed/predicted. Predicted values for FVC and FEV_1 are calculated from equations based on age, height and gender because these characteristics are the most important determinants of lung and airway size in healthy individuals.[14-17] Office spirometers are typically programmed with prediction equations derived from the study of Caucasians, such as the European Community for Steel and Coal (ECSC) (Table III).[17] Caucasians, when compared with indigenous populations, usually show higher FVC and FEV_1, but similar or lower FEV_1/FVC%. The use of inappropriate predicted values can result in an increased rate of abnormal results in clinically normal people.

The use of prediction equations based on studies carried out in South Africa, has been investigated.[18] Indigenous equations, as detailed in Table IV, are, where available, recommended for population screening, surveillance and medico-legal purposes. However, it is acknowledged that the application of these predicted values in every context where spirometry is used may present practical difficulties. Alternatively, office spirometers usually have a facility for application of a correction factor such as 0.9 for adjusting predicted values for Caucasians with a view to their being used for indigenous populations. Adjusted per cent predicted can be calculated using the formula:

$$[\text{Observed}_{\text{indigenous}} / (\text{predicted}_{\text{Caucasian}} \times 0.9)] \times 100]$$

While the use of such correction factors is acceptable, when understood as an approximation, use of the recommended prediction equations is the preferred option. Operators must familiarise themselves with their spirometers regarding these conditions.

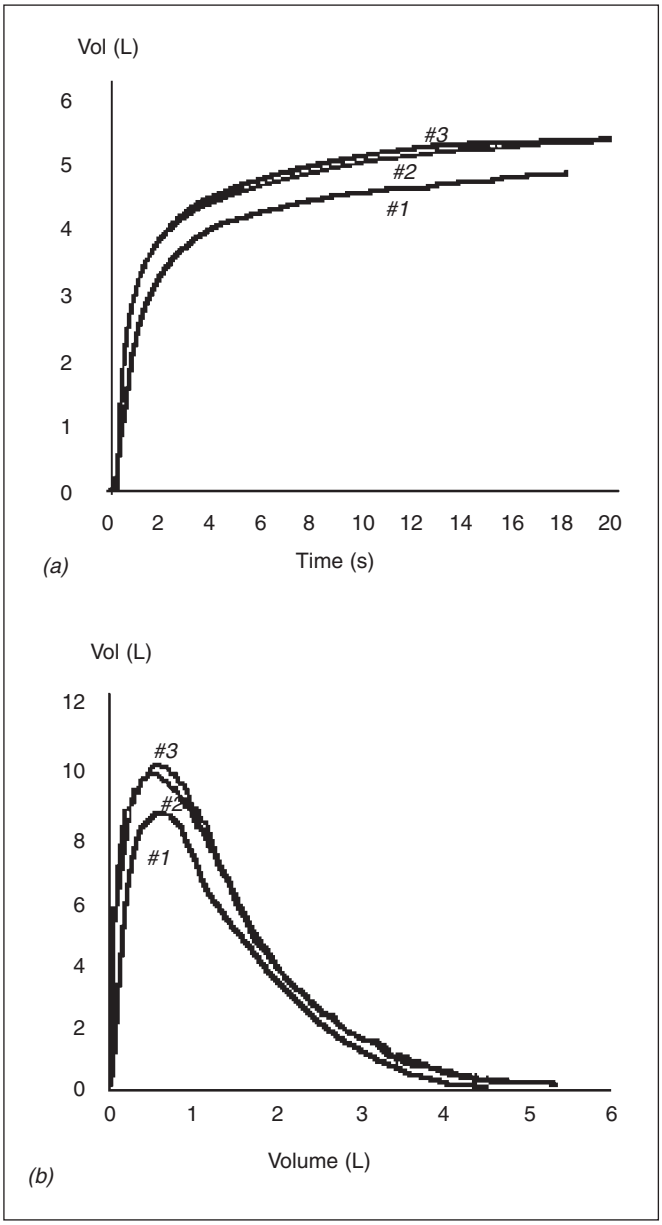

Fig. 5. (a) Volume-time, and (b) flow-volume curves each demonstrating three acceptable FVC trials, only #2 and #3 of which are reproducible.

Table III. ECSC prediction equations* from Quanjer *et al.*[17]

Parameter	Prediction equation	1.64 × RSD
Men		
FEV_1† (l)	4.30H – 0.029A – 2.49	0.84
FVC† (l)	5.76H – 0.026A – 4.34	1.00
FEV_1/VC%	– 0.18A + 87.21	11.8
Women		
FEV_1† (l)	3.95H – 0.025A – 2.60	0.62
FVC† (l)	4.43H – 0.026A – 2.89	0.71
FEV_1/FVC%	– 0.19A + 89.10	10.7

*Valid for age 18 - 70 years. Between age 18 and 25 years substitute age 25 in the equation. The lower limit of normal (LLN) is the lower 5th percentile: predicted value – 1.64 × RSD.
†80% predicted is an accepted alternative LLN.
H = standing height (m); A = age (years); RSD = residual standard deviation.

Table IV. Prediction equations* from Louw *et al.*[5] (African men) and Mokoetle *et al.*[8] (African women)

Parameter	Prediction equation	1.64 × RSD
Men		
FEV_1 (l)	2.9H – 0.027A – 0.54	0.75
FVC (l)	4.8H – 0.024A – 3.08	0.89
Women		
FEV_1 (l)	3.4H – 0.028A – 1.87	0.64
FVC (l)	4.5H – 0.023A – 3.04	0.67

*The lower limit of normal (LLN) is the lower 5th percentile: predicted value – 1.64 × RSD. 80% is an acceptable alternative LLN.
H= standing height (m); A = age (years); RSD = residual standard deviation.

9.3 Diagnosis and severity grade

9.3.1 Algorithm

The major aims of interpreting spirometric results are to confirm the clinical diagnosis and to estimate the severity of the disease. An algorithm is presented (Fig. 6) for categorising spirometric results as obstructive, normal or restrictive patterns. The algorithm employs three variables, namely FEV1/FVC%, % predicted FVC and % predicted FEV_1. The interpretative strategy proposed is based on published guidelines,[19] but the lower limit of normal (LLN) for FEV_1/FVC% has been adapted to conform to current diagnostic guidelines for chronic obstructive pulmonary disease (COPD).[20]

The LLN for FEV_1/FVC%, FVC and FEV_1, is the 5th percentile (see Tables III and IV). Eighty per cent predicted is an acceptable alternative LLN for FVC and FEV_1. The use of a fixed percentage for the LLN for FEV_1/FVC% (usually 70% or 75%) is a pragmatic clinical approach, but has limitations. For screening purposes it may be more accurate to use the 5th percentile to minimise misclassifications of borderline values. A reduced FEV_1 should always be regarded as abnormal. When this is the only finding on the spirogram, further investigations, including a bronchodilator test, may be necessary to define the abnormality (see Fig. 6).

Non-clinicians such as, for example, occupational health nurses can use the algorithm to identify cases for referral. The experienced clinician will use this information in combination with pre-test information, including the indications for testing, and his/her knowledge about the case to make a final clinical diagnosis.

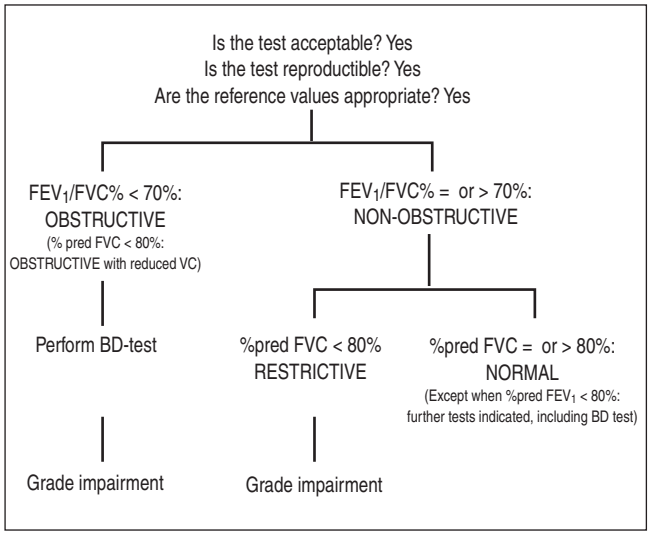

Fig. 6. An algorithm for categorising spirometric results is presented. The observed FEV_1/FVC is expressed as a percentage and the lower limit of normal (LLN) is defined as 70%. FVC and FEV_1 are based on per cent predicted (%pred) and LLN defined as 80% (BD = bronchodilator).

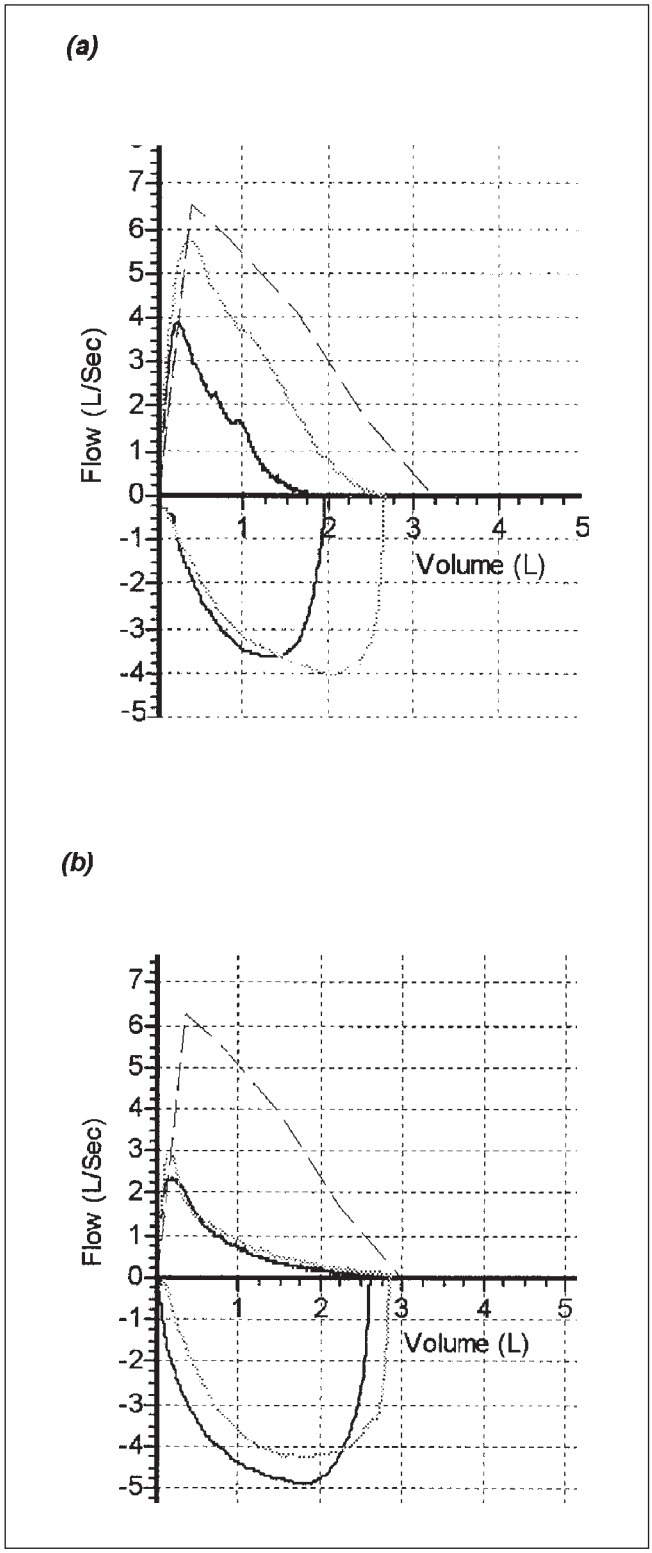

Fig. 7. Flow-volume curves exhibiting typical (a) reversible obstruction in an asthmatic, and (b) non-reversible obstruction in a person with COPD (black = pre-bronchodilator, grey = post-bronchodilator, broken line = reference standard).

9.3.2 Obstructive defect

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. The experienced clinician will readily recognise a pattern of expiratory airflow limitation on the flow-volume curve (Fig. 7). The diagnosis of an obstructive defect should be followed up with a bronchodilator test to examine the nature of the obstruction. Severity of obstruction is graded according to the worst affected spirometric parameter, usually % predicted FEV_1. Mild obstructive defects could be missed if there is under-estimation of FVC due to unacceptable end-of-test criteria.

9.3.3 Restrictive defect

A restrictive ventilatory defect is characterised physiologically by a reduction in total lung capacity (TLC) as determined by advanced lung function testing. One may infer a restrictive defect when FEV_1/FVC% is normal or high (non-obstructive) and FVC is reduced (Fig. 8). The severity of the restrictive defect is graded according to TLC when available, otherwise it is graded according to the worst affected spirometric parameter, and usually % predicted FVC.

A range of conditions can reduce FVC *per se*:

- Conditions impeding movement of the chest wall (e.g. pain, pleural thickening or effusion, neuromuscular weakness, skeletal abnormality or hyperinflation with air trapping as found in COPD).
- Diffuse conditions of lung parenchyma causing stiffness of the lung (e.g. interstitial lung disease with fibrosis, pulmonary oedema).
- Conditions causing reduced communicating lung volume (e.g. lung resection, occlusion of a main bronchus, post-tuberculous lung destruction and space-occupying lesions in the chest).

Restrictive abnormalities are often over-diagnosed because of poor effort by the patient (Figs 3 and 4) or the use of inappropriate prediction equations. Nevertheless, diagnostic interpretation of a reduced FVC can be difficult and referral to a specialist must be considered after exclusion of obvious technical causes.

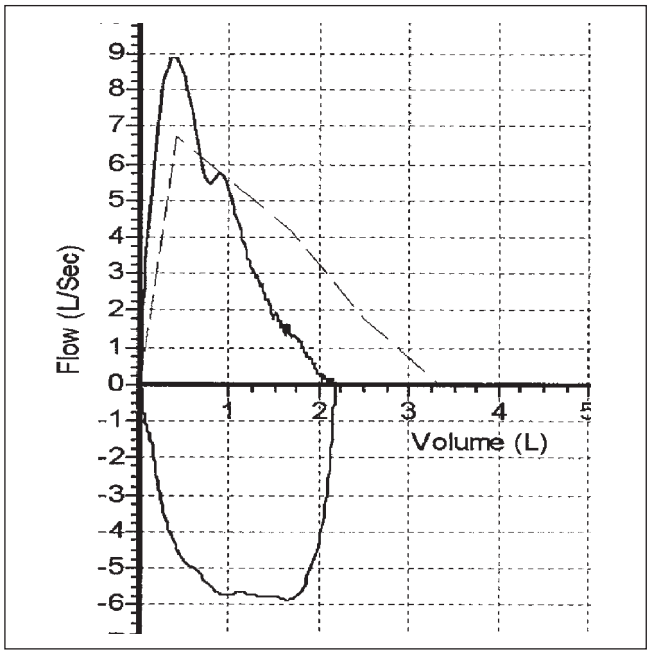

Fig. 8. Flow-volume curve exhibiting a typical restrictive pattern in a person with sarcoidosis (broken line = reference curve). The 'shoulder' on the down-slope of the expiratory curve was reproducible (not demonstrated). It represents a normal physiological phenomenon of the expiratory curve.

9.3.4 Obstruction with reduced FVC

This pattern consists of reduced FEV_1/FVC% and FVC and is usually found in obstructive conditions such as, for example, severe emphysema or asthma, but a combination of an obstructive and restrictive condition can produce a similar result. Other VC manoeuvres (section 8.1) and a bronchodilator test (Fig. 7), performed in the office, can assist in further defining the underlying disease. The severity of the defect is graded according to the indicator showing the most severe defect, usually % predicted FEV_1.

9.3.5 Bronchodilator response

The purpose of a bronchodilator test is to determine whether airway obstruction, as measured by spirometry, is reversible with inhaled beta-2 agonists (Fig. 7). A bronchodilator test can be standardised as follows:

1. Two reproducible FVC trials are obtained from the test subject.
2. Two puffs (400 µg) of salbutamol or equivalent are administered.
3. A waiting period of at least 10 minutes is introduced.
4. Two reproducible FVC trials are again obtained.
5. The best post-bronchodilator FEV_1 is evaluated for a significant improvement of at least 200 ml *and* 12% from the best pre-bronchodilator FEV_1. Per cent improvement in FEV_1 can be calculated using the formula:

$$[FEV_{1\ pre\text{-}BD} - FEV_{1\ post\text{-}BD} / FEV_{1\ pre\text{-}BD}] \times 100$$

The post-bronchodilator FVC trials must be done at least 10 minutes after administration of the bronchodilator, but ideally only after 20 - 30 minutes, as this is the time of maximum effect of most short-acting bronchodilators. Both the pre- and post-bronchodilator FEV_1 must be reproducible; otherwise a response cannot be confidently interpreted as such. For an accurate interpretation of a negative response, subjects must have been weaned from short-acting bronchodilators for at least 4 hours and long-acting bronchodilators and theophylline for at least 12 hours, if medically possible. A number of factors, including the dose of bronchodilator, recent prior bronchodilator medication and timing of the post-bronchodilator FVC trials can influence the magnitude of the

Table V. Guide for grading* spirometric results with a view to quantifying respiratory impairment

Parameter	Normal	Mild (able to meet physical demands of most jobs)	Moderate (diminished ability to meet physical demands of many jobs)	Severe (unable to meet physical demands of most jobs)
% pred FVC	≥ 80	60 - 79	51 - 59	≤ 50
% pred FEV_1	≥ 80	60 - 79	41 - 59	≤ 40
FEV_1/FVC%	≥ 70	60 - 69	41 - 59	≤ 40

*Impairment grade is allocated according to the worst affected parameter. Refer to a pulmonologist if impairment grade and clinical assessment do not agree.

response significantly. Each practice should decide on a standard protocol.

9.3.6 Grading respiratory disease severity

The main indications for grading respiratory disease severity are to quantify respiratory impairment/disability for medico-legal purposes, and to optimise and standardise treatment practices.

Guidelines for grading spirometric impairment correlate different lung function tests, including spirometry, with the ability to perform physical activities.[21] For this purpose criteria for spirometry, performed in the office, are included (Table V) for use in conjunction with the algorithm. LLN for FEV_1/FVC% has been adapted to conform to current diagnostic guidelines for chronic obstructive pulmonary disease (COPD).[20] A severity grade is awarded according to the worst affected parameter. The grading of obstruction should be based on the post-bronchodilator values.

In most cases simple spirometry will be sufficient for evaluating respiratory impairment. However, if discordance is found between spirometry and the stated level of dyspnoea or clinical evaluation, additional lung function tests may be indicated and the subject must be referred to a specialist with diagnostic lung function facilities. Further tests might include carbon monoxide diffusing capacity (DLCO) and/or exercise testing. In addition to spirometry, DLCO is clinically one of the most useful tests of lung function. It is especially useful in interstitial lung diseases, including the pneumoconioses, where gas transfer at alveolar level might be affected disproportionately to the mechanical properties of the lung. Another factor that needs to be considered during the clinical evaluation is the potential contribution of extra-pulmonary disease, for example, ischaemic heart disease, to total impairment. Also, because of its varying nature, the usual spirometric criteria do not apply to asthma as far as assessment of impairment/disability is concerned.[22]

As stated before, treatment guidelines also use spirometric grading to standardise treatment practices. These guidelines for grading severity are usually disease-specific and their main aims are to control the disease and improve prognosis. Therefore, the spirometric grading could differ from general guidelines aimed primarily at quantifying functional impairment.

9.4 Reporting

Spirometry reports must contain the following information:

- Identification of subject and date of testing.
- Personal information (see section 7.2) and origin of reference values.
- Numerical values and graphs to assess acceptability and reproducibility (at least two curves, but preferably three).
- Latest calibration date.

The report should refer to lung function and not disease (e.g. 'obstructive lung function defect without reversibility' rather than 'chronic obstructive lung disease'), unless the reporter is a clinician and has full clinical details to make an appropriate diagnosis.

10. Spirometry Training and Certification Committee

For further information on training opportunities, readers may contact the Chair, Spirometry and Training Certification Committee, South African Thoracic Society, PO Box 16433, Vlaeberg, 8018.

11. Acknowledgement

The Standards of Spirometry Committee of the SATS drafted this document. The SATS Council adopted it in August 2001. The working group wishes to thank all reviewers for their input and the staff of the lung function laboratory at Tygerberg Hospital for help with graphic material.

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