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STANDARDS FOR THE DELIVERY OF SPIROMETRY FOR COAL MINE WORKERS

Thoracic Society of Australia and New Zealand

June 2017



Developed in partnership with



Queensland
Government

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Glossary and abbreviations

ANZSRS	Australian and New Zealand Society of Respiratory Science
ATS	American Thoracic Society
COPD	Chronic Obstructive Pulmonary Disease
ERS	European Thoracic Society
FEV ₁	Forced Expiratory Volume in one second
FVC	Forced Vital Capacity

GLI	Global Lung Initiative
LABA	Long-Acting Beta Agonist
PEF	Peak Expiratory Flow
SABA	Short-Acting Beta Agonist
TSANZ	Thoracic Society of Australia and New Zealand

Definition

WORKER	A coal mine worker presenting for a health assessment
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1.0 INTRODUCTION

1.1 Background

In 2016 an independent review of the respiratory component of the Coal Mine Workers Health scheme was performed by Monash University for the Queensland Department of Natural Resources and Mines. The review was in response to 6 confirmed cases of coal workers pneumoconiosis (Black lung disease) over a 7 month period in 2015. Prior to this time, the Queensland Coal Mine Workers Health Scheme (the Scheme) had not identified any new cases for many years. The outcome of the review was clear, demonstrating significant deficiencies in training of the staff performing spirometry, knowledge of the equipment, performance and interpretation of spirometry. Of the tests reviewed, ~40% were deemed poor quality and did not satisfy current international criteria. Furthermore only 7% of the abnormal tests were correctly identified.

In response to the Monash review, this document has been developed specifically for use in an accreditation program for medical practices that undertake spirometry testing of Queensland coal mine workers. However the standards may also have application in other contexts and to other workers. It closely follows the ATS/ERS spirometry standards document.

1.2 Scope and definitions

This document outlines the required standard for performing spirometry for the assessment and monitoring of coal mine workers' lung function.

This standard provides a framework for the training, procedure, quality control and competency assessment requirements to ensure reliable, quality testing and interpretation of results.

Spirometry is the measurement of air movement into and out of the lungs. It is a dynamic test of ventilatory function, which measures how quickly the lungs empty (flow) and how much air can be moved out of the lungs (volume) during a maximal expiration.

Spirometry, in conjunction with clinical assessment, is used for the diagnosis and monitoring of respiratory abnormalities. Quality results that meet international standards require a calibrated spirometer and trained, competent operators and interpreters.

Spirometry results are determined by lung size, airway calibre and the driving force of the respiratory muscles. Therefore, used in conjunction with clinical assessment, spirometry is an invaluable clinical tool to:

- detect diseases that impair ventilatory function
- assess the severity of any existing impairment
- monitor the effects of intervention, occupational exposure or disease progression

High quality spirometry is vital for accurate interpretation. Lack of adherence to this standard will result in poor quality spirometry which may compromise clinical diagnosis and management.

Key spirometry parameters

Definition	Description
FVC (Litres): Forced Vital Capacity	The maximum volume of air forcefully expired after a maximal inspiration
FEV₁ (Litres): Forced Expiratory Volume in 1 second	The volume of air forcefully expired in the first second of a FVC manoeuvre
FEV₁/FVC (ratio): Forced expiratory ratio	FEV ₁ expressed as a fraction (or percentage) of FVC
PEF (Litres/sec): Peak Expiratory Flow	Maximal expiratory flow achieved

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Other spirometry parameters, e.g. mid expiratory flow ($FEF_{25-75\%}$), that are less clinically relevant when assessing airflow limitation¹, are not addressed in this document, but may be considered for further interpretation. This document addresses expiratory flow and volume, however maximal inspiratory manoeuvres can be used in the investigation of extrathoracic abnormalities².

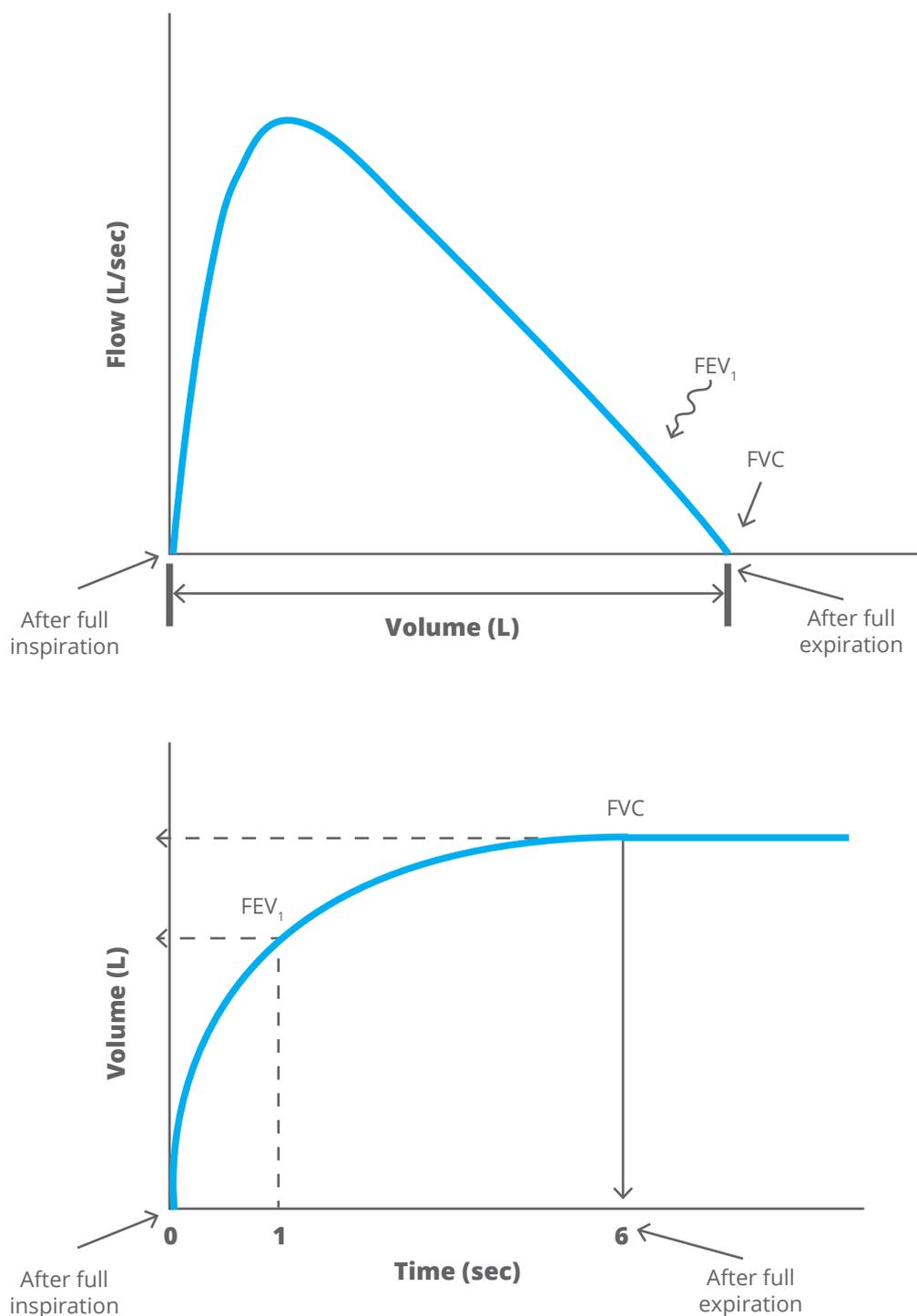


Figure 1. A typical spirometry expiratory flow-volume and volume-time curve from a healthy individual

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2.0 Requirements

The delivery of spirometry assessment requires:

- the provision of appropriate training and competency assessment for personnel,
- calibrated and certified equipment, and
- a high level of continued quality control to ensure reliable and accurate results.

2.1 Personnel

Spirometry can only be performed by a person who has attended and completed the requirements of a training course that meets the *TSANZ Standards for Spirometry Training Courses* specifically developed in partnership with the Department of Natural Resources and Mines.

The operator requires an ability to:

- instruct and motivate the worker to achieve quality results
- identify problems and modify the worker's technique
- maintain quality assurance practice with the equipment and record keeping

Personnel - standards summary

- Attendance at an approved Spirometry Training Course that meets the requirements detailed in the *TSANZ Standards for Spirometry Training Courses* (italicise this title) which was specifically developed in partnership with the Department of Natural Resources and Mines.
- Attainment of course competency requirements; theoretical and practical
- Ongoing demonstration of competency in procedure, interpretation and quality control

Personnel - evaluation of compliance

- Evidence of completion of a Spirometry Training Course that meets the requirements of the *TSANZ Standards for Spirometry Training Courses* (italicised) and ongoing refresher training.
- A one day refresher course must be attended twelve months after the successful completion of the initial training course and then completion of an additional one day refresher course is required every three years thereafter.
- Completion of at least 100 spirometry tests per operator per annum (at least 2 per week). These may be comprised of tests for coal mine workers and from other clients. **Note:** If the figure is less than 100 tests per operator per annum additional reviews of spirometry practice may be required. Practices where operators are unable to achieve at least 70 spirometry tests per operator per annum should not be accredited as spirometry sites.
- A log book of tests is required for each person in the practice conducting spirometry for coal mine workers. A template is available from TSANZ.

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2.2 Equipment

Minimum equipment requirements:

- A dedicated space to conduct the procedure
- A spirometer meeting ATS/ERS requirements⁴
- Nose clips (recommended)
- Single-use bacterial/viral filters, or single-use or disinfected mouthpieces
- Stadiometer and scales for determining height and weight
- Bronchodilator inhaler and single-use spacer for reversibility assessment
- Hard drive storage and printer for data recall and report access
- Certified validated calibration 3L syringe⁴
- Daily access to local atmospheric conditions (including temperature) as per the spirometer specifications.

Modern spirometers typically measure flow, therefore volume is derived as per the equation: Flow (Litres per second) = Volume (Litres) / Time (second). Flow can be measured by a variety of technologies including pneumotachographs, ultrasonic sensors, hot wires and spinning turbines. As the measurement of flow is affected by barometric pressure, temperature and humidity, these values often need to be entered into the spirometer prior to calibration if not directly integrated. The ANZSRS/TSANZ endorsed Spirometer Users and Buyers Guide³ provides detailed information regarding spirometer selection. Regardless of the technology used, the selected spirometer must conform to international standards⁴.

The spirometer requirements:

- Capacity and accuracy requirements⁴, to be provided by the spirometer manufacturer.
- Calibration, or verification of a previous successful calibration, from an annually certified, validated 3L syringe of $\pm 15\text{mL}$ accuracy prior to each testing session or as per manufacturer's recommendation. If not directly integrated, ambient conditions must be entered prior to calibration or verification. Acceptable calibration is a value $\pm 3\%$ of true and should include varying flow rates⁴.
- A regular weekly biological control check by a healthy subject. The calculated "normal" range is between $\pm 2.5\%$ of the mean (average) of at least 10 sessions⁵. If the key parameters fall outside these ranges, preventative maintenance must be instituted and testing must not continue until the fault is rectified and the biological control key parameters are again in the "normal" ranges. These are also important to consider when monitoring workers longitudinally² (see section 4.4).
- Flow-volume displayed in a 2:1 aspect ratio⁴ or volume-time graphical display for visual quality inspection, interpretation and modification of technique if necessary during the test.
- Regular cleaning as per the manufacturer's recommendation.
- An equipment maintenance log⁴: is required and must include:
 - I. Equipment history – with noted use and any changes in hardware, software and reference equations
 - II. Equipment calibration and verification records, including error reports and resulting preventative maintenance
 - III. Biological control record and calculated "normal" ranges



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Equipment standard summary:

- The spirometer meets international standards⁴
- Calibration or verification using a certified syringe prior to each testing session or as per manufacturer's recommendation⁴
- Weekly biological control checks from a healthy subject⁵
- Regular cleaning
- Maintenance of an equipment log⁴

Equipment - evaluation of compliance:

Presentation of an equipment maintenance log that complies with this standard that includes:

- Equipment history – with noted use and any changes in hardware, software and prediction equations
- Equipment calibration and verification records, including error reports and resulting preventative maintenance
- Biological control record and “normal” ranges

2.3 Infection control

Testing workers that may have a communicable disease poses a risk to staff and other workers due to the potential of cross-contamination. Operators must adhere to infection control policies and procedures at all times.

Spirometry equipment has the potential to transmit blood borne and air borne pathogens. It is suggested to delay testing in those with a known or suspected communicable disease until the risk abates.

The risk of cross-contamination is reduced by:

- Regular equipment cleaning
- Good hand-washing hygiene between workers and following equipment handling
- Use of single-use viral/bacterial filters and spacers
- Use of single-use or disinfected mouthpieces
- Use of personal protective equipment (e.g. gloves)

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3.0 Measurement

3.1 Testing sequence

Step 1. Determine the test indication and any contraindications

Determine why the test is being performed and any other specific worker information that may affect the procedure, including contraindications.

Pre-test worker advice includes the avoidance of:

- short acting beta agonists (SABA) for 4 hours
- long acting beta agonists (LABA) for 8 hours

Spirometry is extremely safe. Contraindications include conditions that may be aggravated by forced manoeuvres including:

- Unstable cardiovascular condition
- Thoracic, abdominal, or cerebral aneurysm
- Recent pulmonary embolism
- Recent pneumothorax
- Recent thoracic, abdominal, cerebral or eye surgery.

Those with confirmed or suspected communicable disease or particular discomfort that may affect result quality should delay testing until this abates ⁶.

Step 2. Equipment preparation:

- i. Ensure the equipment is correctly prepared as per the standard (see section 2.2).
- ii. Attach a single-use, disposable filter or mouthpiece, or disinfected reusable mouthpiece to the device.

Step 3. Worker preparation

- i. Measure and document the worker's height (tall and straight without shoes or hat) using a stadiometer, and weight using scales.
- ii. Enter the worker's demographics (height, weight, age, gender, ethnicity) and the type and time of their last inhaler medication into the spirometer's software.
- iii. Ensure the worker is seated comfortably, upright with good posture, feet on the floor and arms uncrossed.
- iv. Explanation and demonstration: It is vital that the worker understands why they are doing the test, and how to perform it. The operator should firstly explain what is being measured. They should then give clear, concise instructions, emphasising the importance that each manoeuvre should be a maximal effort. A demonstration of the required manoeuvre is often helpful.



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Step 4. The test

- Apply a nose clip to ensure mouth breathing (recommended, but not essential).
- **Instruction**

Spirometers have the ability to measure both inspiration and expiration (TYPE A) or expiration only (TYPE B). Both are acceptable but have slightly different instructional methods:

TYPE A: Instruct the worker to:

- I. Seal their lips tightly around the mouthpiece
- II. Breathe a few “normal” tidal breaths
- III. Inspire rapidly, as much air as possible
- IV. When completely full, without delay, expire (“blow”) as hard and as fast as they can until no more air can be expired (in one continuous breath with encouragement to “keep blowing”)

TYPE B: Instruct the worker to:

- I. Inspire rapidly, as much air as possible
 - II. When completely full, and without any air leak, place lips tightly around the mouthpiece without delay (<1 sec)
 - III. Then, expire (“blow”) as hard and as fast as they can until no more air can be expired (in one continuous breath with encouragement to “keep blowing”)
- During the measurement, the worker should maintain an upright posture with lips tightly sealed around the mouthpiece. The operator should coach the worker, and provide encouragement to “keep blowing”. The worker should be continually observed for any rare adverse effects, such as light-headedness.
 - Continued strong verbal encouragement is essential during the measurement. The operator controls the measurement by instructing the worker and critiquing the results to ensure acceptability criteria are met. Worker feedback may be required to improve technique.

Step 5. Test finalisation

Testing is complete when acceptability and repeatability criteria are achieved, or a maximum of 8 trials are attempted (see section 3.2).

Step 6. Operator comment

A comment of test quality is documented to assist interpretation and reporting.

Acceptable and repeatable results provide confidence of test quality. Submaximal and poor efforts will rarely meet these standards. International standards⁴ require at least 3 acceptable manoeuvres and of these, the two best efforts are to be repeatable.

The ability to achieve these standards is improved by continually observing the worker and the flow-volume curves, and by carefully scrutinising the results. Feedback to the worker is required to correct any errors in technique.

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*At least 3 acceptable manoeuvres

Acceptability criteria

- A maximal inspiration prior
- Fast expiration without delay, creating an observed sharp rise in the flow trace. Back extrapolated volume is to be <5% of FVC or <0.15L.
- Maximal continuous expiration for ≥ 6 seconds, with a plateau in flow despite continued effort (<0.025L measured over 1 sec)
- No observed leaks or artefact in the trace

*The two best acceptable manoeuvres are repeatable

Repeatability criteria:

- The two largest FVC values are within 150 mL of each other
- The two largest FEV₁ values are within 150 mL of each other

While not typically used for interpretation, the Peak Expiratory Flow (PEF) is a strong indication of worker effort, and can assist in determining manoeuvre acceptability.

Occasionally, obtaining acceptable and repeatable results is challenging, despite repeated instruction. In these cases, it is recommended not to persist beyond 8 attempts and document comments on test quality.

Many modern spirometers have inbuilt software to indicate acceptability and repeatability which can be helpful, however the operator must understand the concepts of quality spirometry. Software function keys which can be helpful for test progression vary between devices and manufacturers.

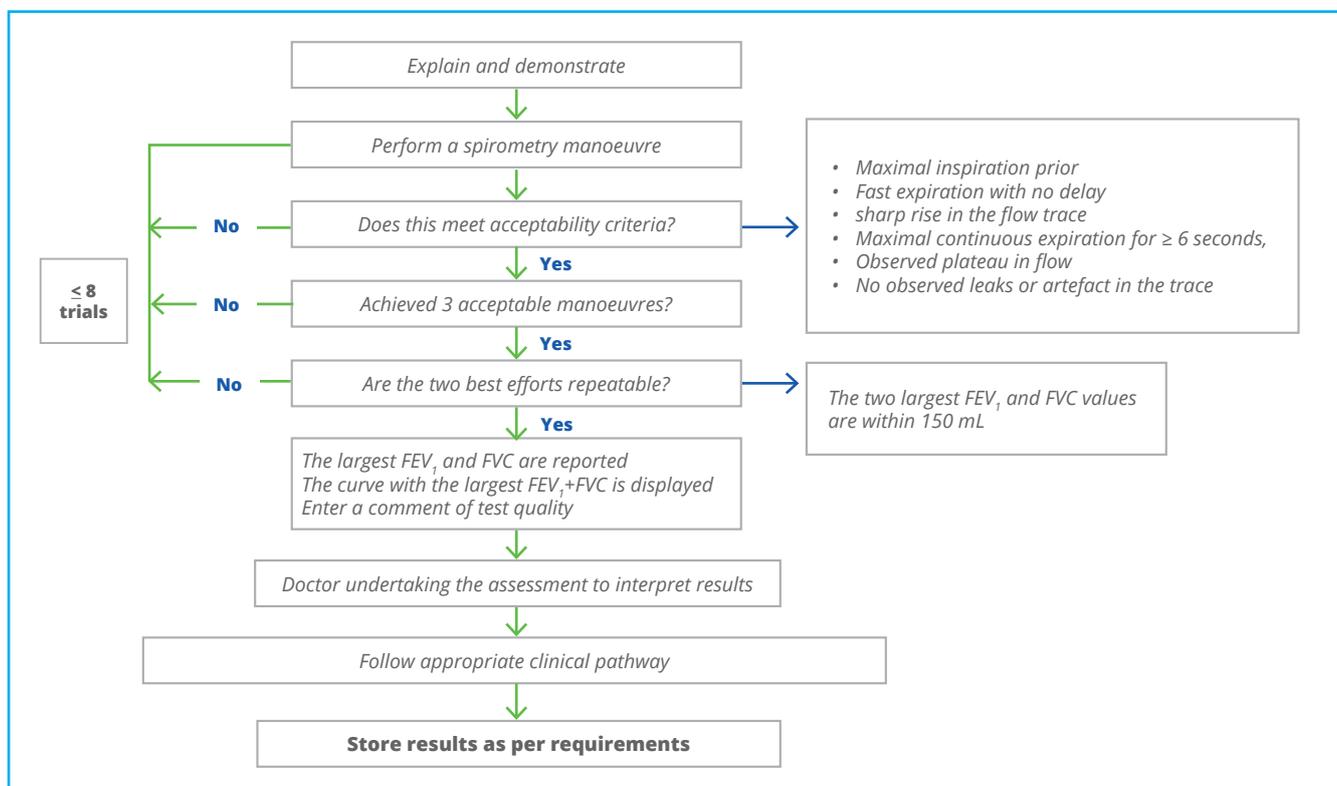


Figure 2. Process for Performing Spirometry for Coal Mine Workers

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Spirometry testing standard summary:

- Worker test indication, demographics and recent medication use is documented
- Worker is comfortable, with full procedure explanation and demonstration
- At least 3 efforts meet acceptability criteria
- The 2 best acceptable efforts are repeatable
- Strong verbal encouragement and feedback is given throughout testing
- No more than 8 trials are attempted

Spirometry testing - evaluation of compliance:

- Documents any potential contraindications
- Correctly documents worker height, weight, gender, age and ethnicity.
- Documents acceptability and repeatability criteria

3.2 Selection of reported results

The largest FEV₁ and FVC from the two repeatable, acceptable efforts are reported for interpretation. These values are used to calculate the reported FEV₁/FVC ratio and may not necessarily be from the same manoeuvre. The flow-volume curve with the largest sum of FEV₁ and FVC is displayed on the report.

3.3 Reversibility

Reversibility is required for all workers having spirometry because coal mine workers are at risk for a wide range of respiratory conditions including occupational asthma. Testing for occupational asthma requires reversibility testing.

- "The test" procedure (see section 4.0) is repeated between 10-20 minutes following the administration of standardised bronchodilator therapy. For optimal effect, it is suggested that 4 separate doses of 100µg of SABA (e.g. salbutamol) be administered by a metered dose inhaler via a spacer at approximately 30sec intervals⁴.
- "Post" bronchodilator values are compared to the baseline "Pre" values in absolute terms (L or mL) and as a percent change from "Pre" values. i.e "Post"- "Pre"/"Pre" x100.
- Best "Pre" and "Post" flow-volume curves are displayed overlaid to provide a visual representation of the response see Figure 5.

Spirometry result standard summary:

- The largest FEV₁ and FVC from the two best repeatable, acceptable trials are reported
- The flow-volume curve from the effort with the largest sum of FEV₁ and FVC is displayed on the report
- Airway reversibility is assessed by comparing "Post" spirometry FEV₁ and FVC (between 10-20 minutes following 4x100µg SABA via spacer) to "Pre"

Spirometry result - evaluation of compliance:

- Documents the method for evaluating airway reversibility
- Correct reporting of FEV₁ and FVC from acceptable trials

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4.0 Reporting and interpretation

While typical patterns of abnormality can be recognised, spirometry used in isolation cannot specifically diagnose a particular condition.

Doctors undertaking health assessment with responsibility for interpreting and reporting of results must also be able to assess and comment on test quality. Spirometry reports and interpretation should be clear, concise, informative² and address the test indication. Final reports and all collected raw data must be securely stored and be easily retrievable for analysis and printing upon request.

The final report must include:

- Worker identification, demographics, time and date of test
- The best flow-volume curve
- The key parameter values in absolute terms
- The response to bronchodilator in absolute terms and percent change
- The expected reference values (as lower limit of normal and mean of the reference [% predicted])
- The operator comment of test quality and bronchodilator administered
- Reference value data set used
- A final interpretation that includes comment on:
 - o Test quality
 - o Indication of normality or abnormality in comparison to reference values.
 - o If abnormal, the suggested pattern and severity of defect (i.e. obstructive, restrictive, mixed or presence of reversibility)
 - o A comparison of any available longitudinal data

4.1 Critique of the key parameters

- A critique of the reported flow-volume curve is required to assess test quality, and provide an initial indication of normality or abnormality (see section 4.2) with consideration of the operator comments.
- FEV₁, FVC and the FEV₁/FVC ratio are the key parameters used for interpretation in their relation to:
 - reference equations
 - previously performed results following:
 - o bronchodilator therapy in the assessment of reversibility
 - o an intervention or occupational exposure
 - o longitudinal monitoring of known disease



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Reference values

Reference equations are derived from healthy populations to provide an indication of what is expected for the worker according to their height, age, gender and ethnicity. Key parameters are directly compared to the lower limit of normal and as a percentage of the mean reference value (% predicted). At the date of this publication, the reference ranges of the Global Lung initiative (GLI)⁷ must be utilised as per TSANZ and ANZSRS recommendations. This a modern international dataset that includes a broad selection of healthy people, with considerations for particular ethnicities.

4.2 Typical patterns of respiratory abnormality

Airflow obstruction

The worker is unable to expire quickly, i.e. airflow limitation, implying airway narrowing. This can be due to excess mucus production, airway wall thickening, inflammation and bronchial smooth muscle contraction, features occurring in asthma and chronic bronchitis, or dynamic collapse of the airways, as in chronic obstructive pulmonary disease.

- FEV₁/FVC ratio below the lower limit of normal
- There is a distinct concave appearance of flow-volume curve

Restriction

The worker has a reduction in total lung capacity. This can occur in those with pulmonary fibrosis, pleural/ chest wall disease or weak respiratory muscles. While spirometry can reflect a restrictive pattern, diagnosis requires confirmation with more complex lung volume measurement of total lung capacity following referral to a specialist respiratory facility.

- FVC is below the lower limit of normal
- The FEV₁/FVC ratio is normal or high
- There is a distinct reduction of volume evident on the flow-volume curve
- Diagnosis requires confirmation from a specialist respiratory facility

Mixed abnormalities

The worker has co-existing airway obstruction and restriction.

- The FEV₁/FVC ratio and FVC are below the lower limit of normal
- FEV₁ % predicted is reduced
- There is a distinct concave appearance of flow-volume curve with reduced volume
- Diagnosis requires confirmation from a specialist respiratory facility

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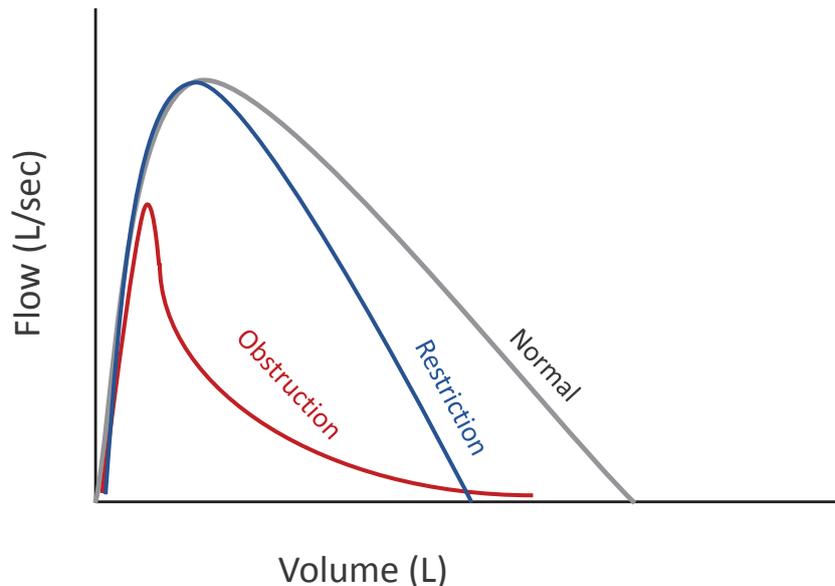


Figure 3. Visual representation of flow-volume curves in a healthy normal subject and in an obstructive and restrictive ventilatory abnormality

Algorithm for Interpretation of Spirometry in Coal Workers

- **FEV₁/FVC** ratio is initially consulted to identify any airway obstruction
- **FEV₁ % predicted** is used to classify the severity of any obstruction
- **FVC % predicted** is then used to determine any suggestion of restriction.

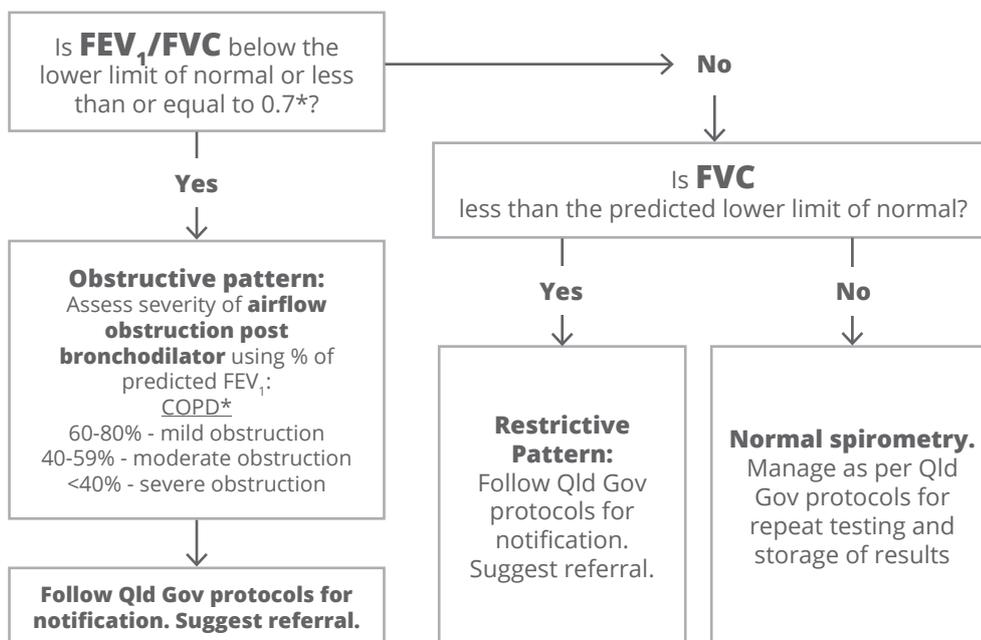


Figure 4. Interpretation algorithm relating to Coal Mine Workers

*COPD-X Plan 2016⁸



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4.3 Reversibility

Reversibility is required for all workers having spirometry testing because coal workers are at risk for a range of occupationally acquired respiratory conditions, including occupational asthma. Testing for asthma requires reversibility testing.

Bronchial responsiveness to bronchodilator inhaler involves integrated responses from the epithelium, nerves, mediators and bronchial smooth muscle². An individual's response to bronchodilator is assumed to test their underlying bronchial hyper-responsiveness, seen most commonly in people with asthma, in addition to potential therapeutic benefits of bronchodilator therapy.

- Reversibility is performed and reported as per the standard (see section 3.4)
- A $\geq 12\%$ and $> 200\text{mL}$ improvement of FEV_1 or FVC from baseline is considered significant reversibility by international standards².

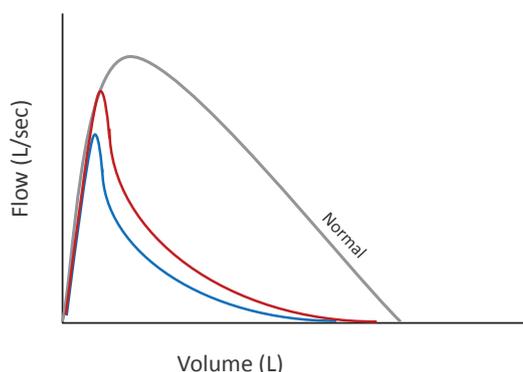


Figure 5. Visual representation of airway reversibility with overlaid “Pre” (blue) and “Post” (red) bronchodilator flow-volume curves.

4.4 Longitudinal monitoring

It can be particularly relevant to evaluate an individual's lung function over time rather than to singularly compare to reference equations. This includes monitoring known abnormalities or assessing the effect of an intervention or occupational exposure.

A meaningful change is greater than the inherent variability of the measure, which tends to be greater over weeks to months, than daily in biological controls. This highlights the importance of calculating the “normal” variation in biological controls (see section 2.2).

A variation in FEV_1 or FVC outside the “normal” variation, or as listed below, is considered a significant change and the appropriate clinical pathway should be followed. The interpretation of such is dependent on adherence to the equipment and procedure quality control standards and requires individual clinical context.

Table 1. Reported significant changes in forced vital capacity (FVC) and forced expiratory volume in one second (FEV_1) over time in the same individual²

	% change in FVC	% change in FEV_1
Within a day		
Normal subjects	≥ 5	≥ 5
Obstructed workers	≥ 11	≥ 13
Week to week		
Normal subjects	≥ 11	≥ 12
Obstructed workers	≥ 20	≥ 20
Year to year	≥ 15	≥ 15

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Spirometry and interpretation standard summary:

- The key parameters are compared to modern reference equations (GLI 2012)⁷
- The flow-volume curve is critiqued for quality, and pattern recognition
- Key parameters are interpreted utilising the algorithm
- Assessment of airway reversibility and/or longitudinal monitoring
- The final interpretation is concise and addresses the test indication
- The final report adheres to the standard
- Data is securely stored with ability to retrieve raw data

Spirometry reporting and interpretation - evaluation of compliance:

The final report must include:

- Worker identification, demographics, time and date of test
- The best flow-volume curve
- The key parameter values in absolute terms
- The response to bronchodilator in absolute terms and percent change
- The expected reference values (as lower limit of normal and mean of the reference [% predicted])
- The operator comment of test quality
- Reference value data set used
- A final interpretation that includes comment on:
 - o Test quality
 - o Indication of normality or abnormality from extrapolation of reference equations
 - o If abnormal, the suggested pattern and severity of defect (i.e. obstructive, restrictive, mixed or presence of reversibility)
 - o A comparison of any available longitudinal data



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5.0 Common causes of poor spirometry

Competency in performing spirometry includes the ability to identify poor quality efforts, sources of error and troubleshoot problems. This section provides examples of common worker-related reasons for poor, unacceptable spirometry manoeuvres.

Acceptable manoeuvres superimpose well when overlaid (e.g. Figure 6a). The hallmark of unacceptable efforts is variability both in the shape of the curves and in the values recorded. Successful modification of poor technique by operator feedback is highly achievable if the operator can identify the source of error, and instruct the worker to modify their technique before repeating the test. Visual inspection of the flow-volume trace can clearly identify poor technique in most cases.

Examples of worker-related poor, unacceptable spirometry

- Glottic closure (e.g. Figure 6 b)
- Submaximal or variable efforts (e.g. Figure 6 c)
- Hesitation at the start of the expiration i.e. slow start (e.g. Figure 6 d)
- Cough in the first second of expiration (e.g. Figure 6 e)
- Submaximal inspiration or expiration (e.g. Figure 6 f)
- Mouth leaks
- Obstruction from tongue/teeth
- Poor posture, especially excessive leaning forward
- Lack of understanding/compliance
- Vocalisation

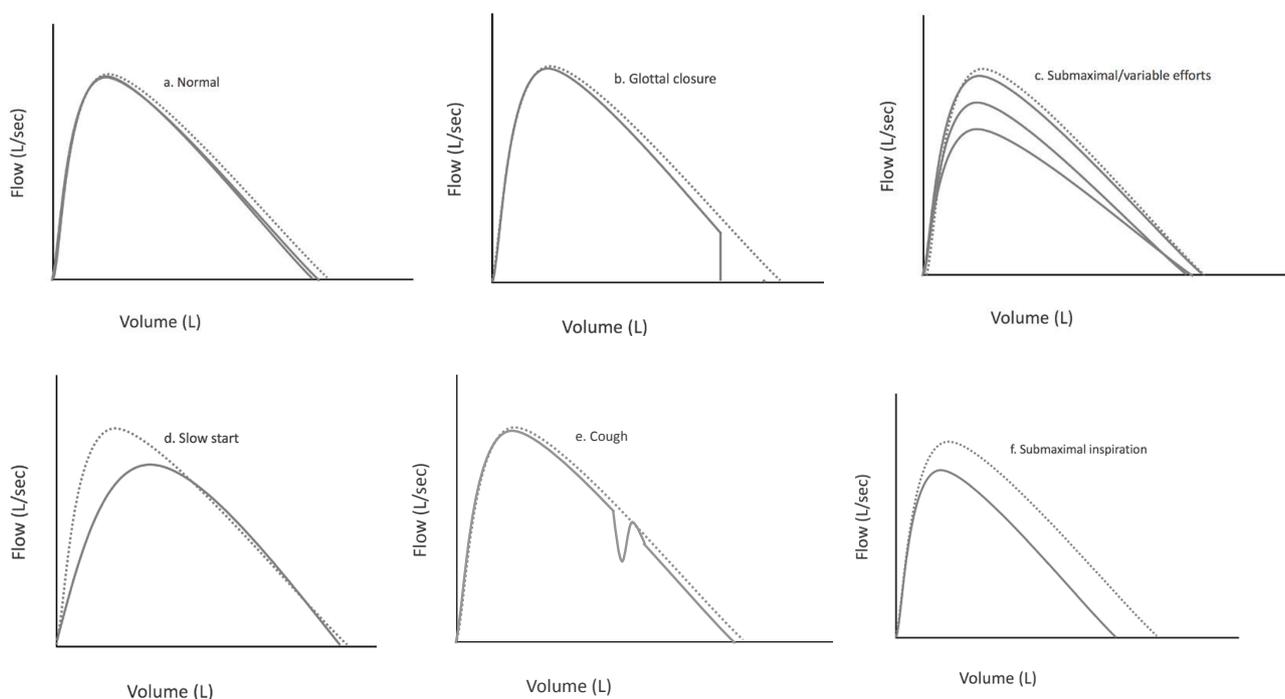


Figure 6. Visual representation of flow-volume curves showing normal (a) and poor spirometry. Dotted line is expected normal curve

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6.0 Summary of required record keeping

Personnel log:

- Documentation of spirometry training course attendance
- Number of tests performed and logbook completion

Equipment maintenance log:

- Equipment history – with noted use and any changes in hardware, software and prediction equations
- Equipment calibration and verification records, including error reports and resulting preventative maintenance
- Biological control record and “normal” ranges

Worker data:

- Final interpreted reports that meet the standard
- Ability to access raw data
- Ability to print data
- Stored securely with worker confidentiality considerations



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7.0 References

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