The Thoracic Society of Australia & New Zealand
LEADERS IN LUNG HEALTH

STANDARDS FOR THE DELIVERY OF SPIROMETRY FOR RESOURCE SECTOR WORKERS

Thoracic Society of Australia and New Zealand

2022

Developed in partnership with

Resources Safety & Health Queensland

Contents

Glossary of abbreviations and definitions

ANZSRS	Australian and New Zealand Society of Respiratory Science
ATS	American Thoracic Society
COPD	Chronic Obstructive Pulmonary Disease
ERS	European Respiratory Society
FEV_1	Forced Expiratory Volume in one second
FVC	Forced Vital Capacity
FIVC	Forced Inspired 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
WORKER	A resource sector worker presenting for a health assessment.
CALIBRATION	The comparison of measurement values delivered by the spirometer with those of a calibration standard of known accuracy. Calibration may be manual or automatic.
VERIFICATION OF CALIBRATION	The process of establishing documentary evidence demonstrating that automatic calibration has achieved the required level of level of compliance during calibration.

1.0 Introduction

Background

In 2016, an independent review of the respiratory component of the Coal Mine Workers' Health Scheme (the Scheme) was performed by Monash University for the (then) Queensland Department of Natural Resources and Mines, now Resources Safety & Health Queensland (RSHQ)[1]. The review was in response to six confirmed cases of Coal Workers' Pneumoconiosis (Black Lung Disease) over a seven-month period in 2015. Prior to this time, the Scheme had not identified any new cases for many years.

The Monash review evaluated 260 spirograms from coal mine workers for quality and accuracy. Of these, four were illegible and 102 were deemed unable to be interpreted due to poor quality testing. Of the remaining 154 spirograms, 30 were identified as abnormal by the reviewers, however, only two of these 30 had been identified as abnormal by the medical advisers within the Scheme[1]. 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.

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 resource sector workers. However, these standards may also have application in other contexts and to other workers. These standards closely follow the 2019 ATS/ERS spirometry standards document[2].

Scope and definitions

This document outlines the required standard for performing spirometry for the assessment and monitoring of lung function in resource sector workers.

These standards provide a framework for the training, procedure, quality control and competency assessment requirements to ensure reliable, quality testing and interpretation of results. **Numbered items in these standards are a mandatory requirement and must be met by providers.**

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; and
- monitor the effects of intervention, occupational exposure or disease progression.

High quality spirometry is vital for accurate interpretation. Lack of adherence to these standards will result in the delivery of 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.
FEV_1 (Litres): Forced Expiratory Volume in one second.	The volume of air forcefully expired in the first second of a FVC manoeuvre.
FEV_1/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.

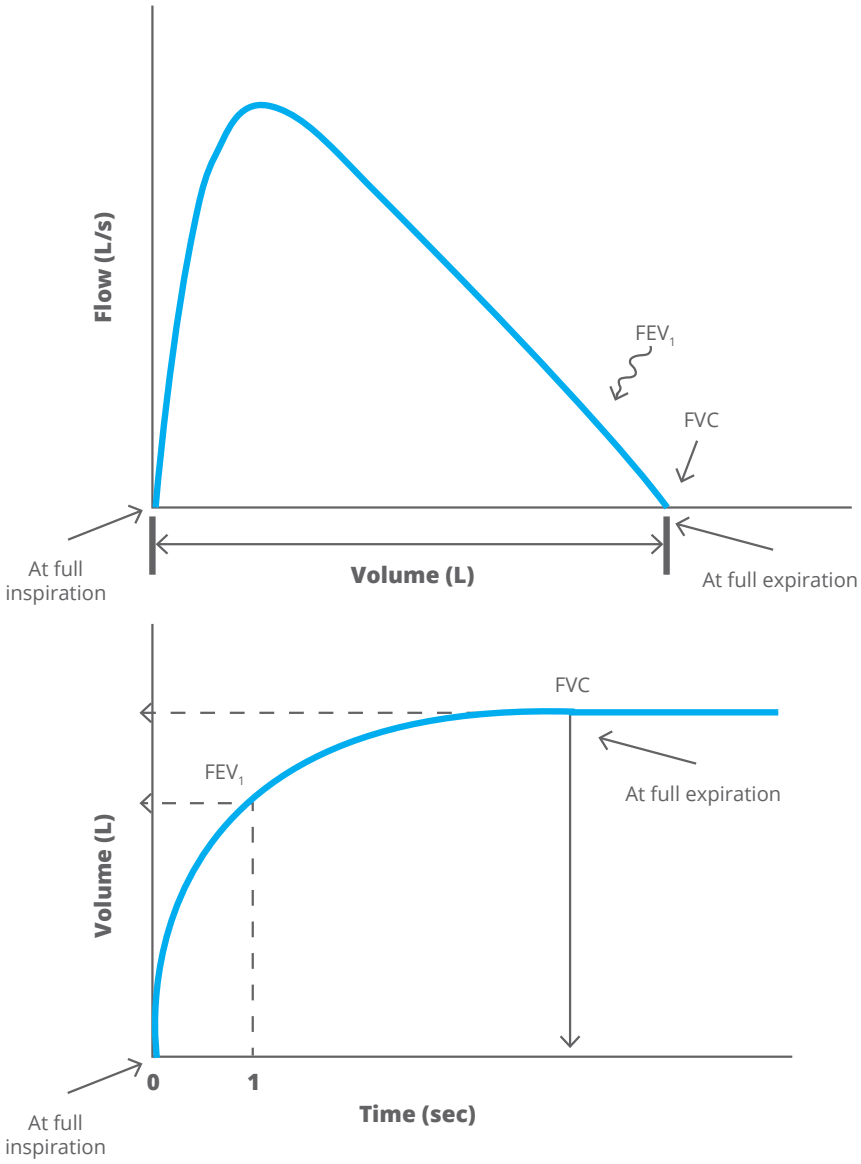


Figure 1. A typical spirometry expiratory flow-volume and volume-time curve from a healthy individual.

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

2.1.1. Spirometry should 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. In Queensland, operators testing spirometry of workers must complete a registered spirometry course as part of the practice's registration requirements with RSHQ.

The operator requires an ability to:

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

There is strong evidence that spirometry quality significantly improves with frequent performance, therefore, spirometry must be conducted by the operator regularly. A benchmark of 100 spirometry tests per operator, per annum, conducted regularly has been established by an expert panel of TSANZ and ANZSRS members for maintenance of currency and competence. This benchmark has been established with reference to the findings of the Monash report and expert consensus opinion.

2.1.2. Personnel conducting spirometry testing must provide evidence that they are conducting spirometry at a rate that will achieve 100 tests per annum. These tests may be from resource sector workers and other clients. A logbook of tests is required for each person in the practice conducting spirometry for resource sector workers. No allowance is made for casual or part time staff as competency and currency of practice are both considered necessary. A template is available from TSANZ.

2.1.3. A one-day refresher course must be attended within 12 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.

2.2 Equipment and space requirements

2.2.1. A dedicated space to conduct the procedure with appropriate access and egress for a medical response in the event of an emergency is required. A stable chair with arm rests in which to seat the worker during the test is recommended over performing the test in a standing position.

2.2.2. Resuscitation equipment must be readily accessible.

2.2.3. A spirometer meeting ATS/ERS requirements[2].

2.2.4. Single-use mouthpieces incorporating bacterial/viral filters are preferred. Single-use one-way mouthpieces may be used. Single use nose clips are recommended.

2.2.5. Stadiometer and scales for determining height and weight. These must be verified to be accurate annually.

2.2.6. Bronchodilator inhaler and single-use spacer for bronchodilator responsiveness assessment (if required).

2.2.7. Appropriate system/s to store raw spirometry data in line with applicable Australian Government requirements on data security and privacy. A printer may be required if hard copies of reports are being produced.

2.2.8. A 3L calibration syringe certified as being accurate to ATS/ERS specifications within the past 12 months[2].

2.2.9. Access to local atmospheric conditions (including temperature) as per the spirometer specifications on the day of testing.

Modern spirometers typically measure flow, therefore volume is derived as per the equation: Flow (Litres per second) = Volume (Litres)/Time (seconds). 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 must be entered into the spirometer prior to commencing testing if not automatically integrated by the spirometer. Regardless of the technology used, the selected spirometer must conform to international standards[2].

2.3 The spirometer requirements

Spirometers must meet the following requirements:

2.3.1. Capacity and accuracy requirements, with written confirmation to be provided by the spirometer manufacturer.

2.3.2. Calibration is the procedure for establishing the relationship between sensor-determined values of flow or volume and the actual flow or volume. A calibration verification is different from calibration and is the procedure used to verify that the device is within calibration limits, e.g., ±3% of true value. Calibration, or calibration verification, should be performed utilising an annually certified, validated 3L syringe with a ±15mL accuracy before each testing session, or as per manufacturer's recommendation. Spirometers which have the capacity for auto-calibration should be verified as required and in line with current best practice and manufacturers' recommendations.

If not directly integrated, ambient conditions must be entered before calibration or calibration verification. Acceptable calibration is a value ±3.0% of true value and should include varying flows. If this is not achieved, the verification must be reattempted. If the device continues to fail calibration verification, seek maintenance support from your supplier. In this instance, the device must not be used for worker testing.

2.3.3. Biological controls can be used to determine if there is a technical issue with spirometry equipment during testing periods. Biological controls are not a replacement for the routine calibration and verification (as detailed here) of spirometers with a calibration syringe.

If used, a biological control program should include one or more healthy, non-smoking staff member (see break out box for details) to assess their own spirometry values approximately once every four weeks. Should a spirometer be suspected of being out of calibration or experiencing issues with volume drift, biological controls can be used as a problem-solving tool for troubleshooting. The calculated "normal" range of ±15% of the absolute FEV_1 or FVC values has been defined as the trigger for further assessment. If the biological control measures exceed 15% of the averaged measures, a repeat verification check should be performed and must be satisfactory before further testing. If the device does not pass calibration or verification (as appropriate), testing must not continue until the fault is rectified.

Flow-volume is to be displayed in a 2:1 aspect ratio or volume-time graphical display for visual quality inspection, interpretation and modification of technique if necessary, during the test.

2.3.4. Regular cleaning is required as per the manufacturer's recommendation.

2.3.5. An equipment maintenance log[2] is required and must include:

2.3.5a. Equipment history—with noted use and any changes in hardware, software and reference equations.

2.3.5b. Equipment calibration and verification records, including error reports and resulting preventative maintenance.

2.3.5c. If used biological control data and the calculated "normal" ranges must be recorded.

Guide to conducting biological control checks

The following advice on the use of a biological control program is provided

- Individuals within a biological control program must be healthy, non-smokers and free of known respiratory disease.
- Spirometry of the biological control should be recorded every working day at approximately the same time of day. A minimum of 10 recordings is required and should be obtained in as short a time as possible, allowing for normal working patterns.
- Calculate the mean (average) for each spirometry parameter: i.e, add up all the readings for that parameter and divide by the number of recordings (e.g., mean 3.60 L). Calculate 15% of the mean (i.e., 3.6 x 0.15 = 0.54 L).
- Finally, obtain the normal range for repeated measurements by adding and subtracting this 15% value to the mean value (i.e., 3.60 - 0.54 = 3.06 L, and 3.60 + 0.54 =4.14 L so the acceptable range for the person tested would be 3.06 L to 4.14 L). You can now use this individual and this range as a guide to verify the accuracy of your spirometer.
- If used, these data must be recalculated every two years to account for normal age-related decline in lung function.

2.4 Mobile spirometry testing requirements

In addition to meeting the requirements detailed in Sections 2.1, 2.2 and 2.3, when performing mobile spirometry testing the following requirements must be met:

2.4.1. Spirometer and calibration syringe must be safely secured in appropriately padded transportation equipment to limit any physical impact which could lead to measurement inaccuracies.

2.4.2. Any spirometer or calibration syringe that has been subject to physical damage during transit (i.e., knocked or dropped) must not be used for testing and will require re-certification from the manufacturer.

2.4.3. Allow calibration syringe to come to same ambient temperature as the spirometer prior to the spirometer being calibrated and/or verified.

2.4.4. Update ambient conditions (barometric pressure, temperature and relative humidity) of testing location in spirometer software prior to mobile testing session.

2.4.5. Calibration and/or verification using a certified syringe must be conducted prior to each mobile testing session as per manufacturer's recommendation.

2.5 Infection control

Testing workers who may have a communicable disease poses a risk to staff and other workers due to the potential of cross-contamination.

2.5.1. Spirometry services must have appropriate infection control policies and procedures. Operators must always adhere to these policies and procedures.

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, e.g., current chest infection, influenza, etc. The risk of cross-contamination is reduced by:

- regular equipment cleaning as per manufacturer's instructions. Equipment cleaning must be performed between each test session.
- staff and workers undertaking hand-washing hygiene before and after testing.
- use of single-use viral/bacterial filters (or mouthpieces as relevant), nose clips and spacers.
- use of personal protective equipment (e.g., gloves).
- Sterilisation of re-usable equipment as per manufacturer's guidelines may be an acceptable alternative to single use equipment.

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.

Respiratory medications can affect spirometry outcomes. Workers should be advised to avoid the following treatments for the periods indicated before spirometry testing[2]. If there is doubt regarding clinical status deferral of testing may be warranted.

- short-acting beta agonists (SABA)—four to six hours.
- long-acting beta agonists (LABA)—24 hours.
- short-acting muscarinic antagonist (SAMA)—12 hours.
- Ultra-LABA—36 hours.
- Long-acting muscarinic antagonist (LAMA)—36 to 48 hours.

Spirometry is extremely safe. Relative contraindications include conditions that may be aggravated by forced manoeuvres including[2]

- unstable cardiovascular condition.
- thoracic, abdominal, or cerebral aneurysm.
- recent pulmonary embolism.
- recent pneumothorax.
- recent thoracic, abdominal, cerebral or eye surgery.
- confirmed or suspected communicable disease.
- physical discomfort resulting from spirometry testing.

A full list of potential relative contraindications can be found in the ATS/ERS Standardisation of Spirometry 2019 Update[2]. If appropriate, testing can be delayed on the advice of the relevant healthcare provider.

Step 2. Equipment preparation

Ensure the equipment and testing area are correctly prepared as per the Standard (see Sections 2.2 and 2.3).

Attach a single-use, disposable filter or mouthpiece, or disinfected reusable mouthpiece to the device.

Step 3. Worker preparation

Measure and document the worker's height (tall and straight without shoes or hat) in centimetres to one decimal place using a stadiometer, and weight in kilograms using scales to nearest 0.5 Kg.

Enter the worker's demographics (height, weight, age (each must be reported to one decimal place), biological sex, and ethnicity. Information regarding the use of asthma medications (Nil or the type, dose and time of last use) must be entered into the spirometer's software and included in the spirometry report. If bronchodilator testing is performed the type and dose of bronchodilator delivered and the time between delivery and post-bronchodilator spirometry must be included in the spirometry report.

Ensure the worker is seated comfortably, upright with good posture, feet on the floor and arms uncrossed.

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.

Step 4. The test

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

Instruction

Spirometers can 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 and without delay (≤2seconds is acceptable) to 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").

V. Inspire at maximal flow back to maximum lung volume

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 (≤2sec).

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. Feedback to worker may be required to improve technique.

Inspiratory Loops: Once the worker has expired all of the air, some spirometers will be capable of recording the inspiratory loop (FIVC). If inspiratory loops are measured, then FIVC - FVC must be ≤0.100 L or 5% of FVC, whichever is greater. Should this criterion not be achieved, the inspiratory loop part of the test is unacceptable and will require repeating with an emphasis on instructing the worker to inspire fully before the forced expiration.

Step 5. Test finalisation

Testing is complete when all acceptability and repeatability criteria are achieved, or a maximum of eight trials pre- and (if necessary) eight trials post-bronchodilator are attempted.

Step 6. Operator comment

The operator must enter information regarding the client's use of asthma medications (Nil or the type, dose and time of last use) into spirometry software and ensure that this information is displayed on the spirometry report. If bronchodilator testing is performed the type and dose of bronchodilator delivered and the time period between delivery and post-bronchodilator spirometry must be included in the spirometry report.

A comment of test quality must be documented to assist interpretation and reporting. The spirometry report and operator's comments must report on the quality of both FEV_1 and FVC in line with international standards[2].

Acceptable and repeatable results provide confidence of test quality. Submaximal and poor efforts will rarely meet these standards. International standards require **at least three acceptable manoeuvres and that both FEV_1 and FVC achieve the required repeatability criteria[2]**

The ability to achieve the required acceptability and repeatability criteria (see break out boxes) is improved by continually observing the worker and the flow-volume or volume-time curves, and by carefully scrutinising the results. Feedback to the worker is required to correct any errors in technique.

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

An **acceptable** manoeuvre must be achieved at least three times and is acceptable only if it **achieves all** of the following acceptability criteria[2]:

- a maximal inspiration prior to the forced expiration.
- fast expiration without delay, creating an observed sharp rise in the flow trace. Back extrapolated volume is to be =<5% of FVC or <0.10L, whichever is greater.
- maximal continuous expiration with a plateau in flow despite continued effort (<0.025L measured over one sec) OR
- achieved expiratory time ≥ fifteen seconds OR
- the individual cannot expire long enough to achieve a plateau and the FVC is within 0.15L of or is greater than the largest prior observed FVC.
- no observed leaks or artefact in the trace.
- if performing inspiratory loops, FIVC must not be >=0.10L or >5% of FVC, whichever is greater.

A testing session is deemed to be **repeatable** if the following is achieved[2]:

- ≥ 2 acceptable FVC values are within 0.15L of each other; and
- ≥ 2 acceptable FEV_1 values are within 0.15L of each other.

Operators are encouraged to obtain at least three acceptable and repeatable efforts where possible to maximise the confidence in the final result.

Operators must work to achieve a minimum quality grade of B or higher for FEV_1 and FVC (see below). Spirometry efforts of lower quality must be noted.

Operator grading guide for reporting spirometry.

Grade	Number of Measurements	Repeatability
A	≥3 acceptable	Within 0.150 L
B	2 acceptable	Within 0.150 L
C	≥2 acceptable	Within 0.200 L
D	≥2 acceptable	Within 0.250 L
E	≥2 acceptable	> 0.250 L
	OR 1 acceptable	N/A
U	0 acceptable AND ≥1 usable	N/A
F	0 acceptable and 0 usable	N/A

Operators must grade measures of FEV_1 and FVC separately

The repeatability grade is determined for the set of pre-bronchodilator manoeuvres and the set of post-bronchodilator manoeuvres separately. The repeatability criteria are applied to the differences between the two largest FVC values and the two largest FEV_1 values.

Grade U indicates that only usable but not acceptable measurements were obtained. Although some manoeuvres may be acceptable or usable at grading levels lower than A, the overriding goal of the operator must be to always achieve the best possible testing quality for each patient.

Definition of abbreviation: N/A = not applicable. Adapted from ATS/ERS Standardisation of Spirometry 2019 Update[2]

Occasionally, obtaining acceptable and repeatable results is challenging, despite repeated instruction. In these cases, it is recommended not to persist beyond eight attempts pre- and (if required) eight attempts post-bronchodilator. If acceptable and repeatable results cannot be obtained, consideration for repeating testing on another occasion may be appropriate. The operator must document comments on test quality.

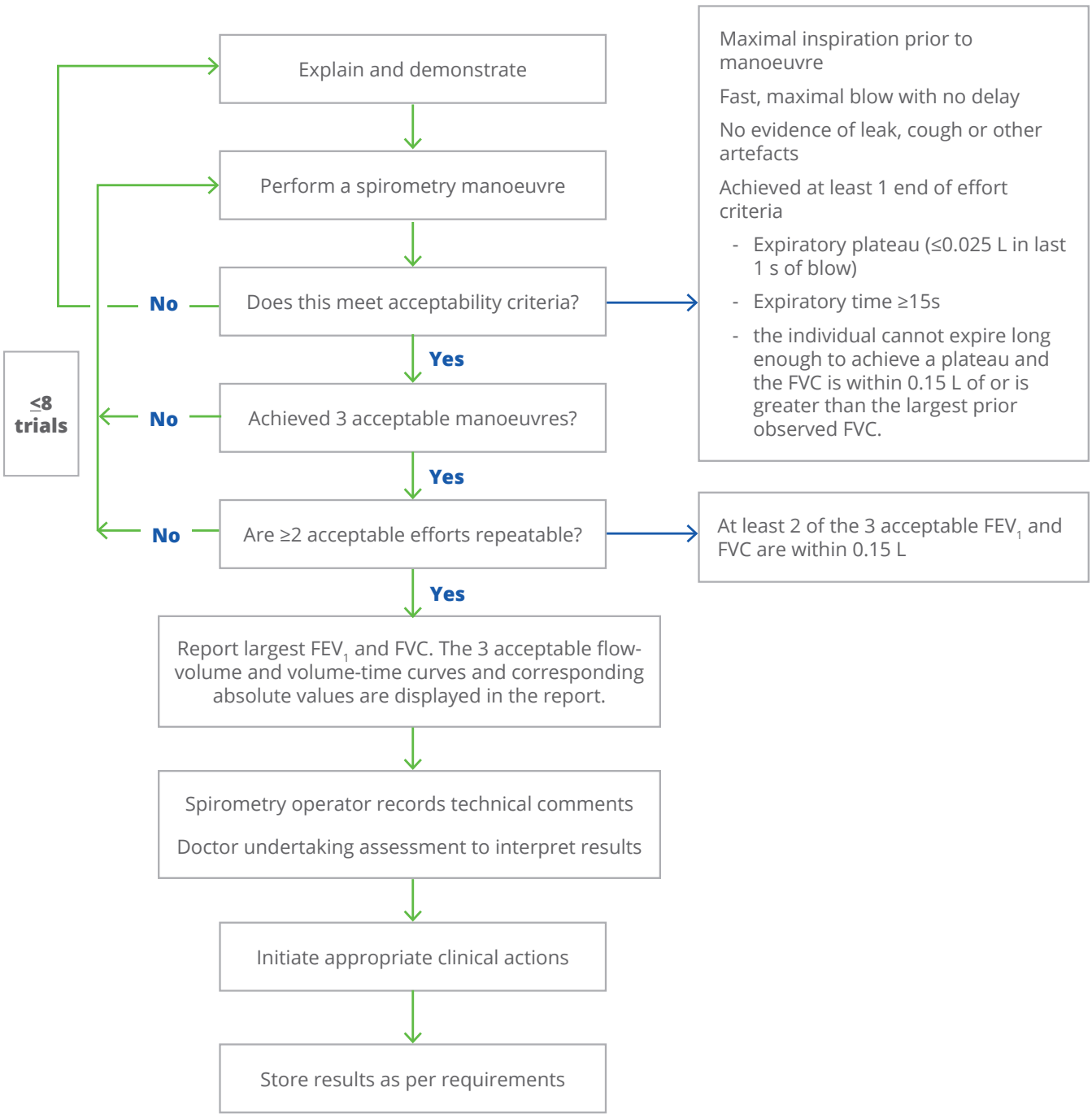


Figure 2. Process for Performing Spirometry for Resource Sector Workers.

3.2 Selection of reported results

3.2.1. The largest FEV_1 and FVC from all of the acceptable efforts are utilised for interpretation. These values are used to calculate the reported FEV_1/FVC ratio and may not necessarily be from the same manoeuvre.

3.2.2. The absolute values from at least three acceptable manoeuvres must be displayed on the spirometry report (if bronchodilator responsiveness testing is performed, the three acceptable "Pre" and three acceptable "Post" values are displayed. See sample report).

3.3 Bronchodilator responsiveness testing

The decision to conduct bronchodilator responsiveness testing is a clinical one that should be considered especially when asthma or other obstructive conditions are suspected. Spirometry services must have standard operating procedures on how this is managed within their practice. This may include the performance of bronchodilator responsiveness testing for workers with documented lung disease, or for those individuals with abnormal spirometry results (defined as FEV_1, FVC or FEV_1/FVC less than the lower limit of normal), irrespective of documented medical history.

3.3.1. If bronchodilator testing is performed the following procedure is commonly used within the Australian clinical context. It remains the responsibility of the reporting healthcare provider and the spirometry service to stipulate what procedure is used in their practice.

- Spirometry is repeated at least 15 minutes following the administration of standardised bronchodilator therapy. For optimal effect, it is suggested that four separate doses of 100µg of SABA (e.g., salbutamol) be administered (as below) by a metered dose inhaler via a spacer at approximately 30 second intervals[2,3].
- After a gentle and incomplete expiration, actuate the SABA metered dose inhaler at the beginning of a slow inhalation to TLC from a spacer. The breath is then held for 5–10 seconds before the patient exhales.

3.3.2. The spirometry report or linked clinical records [as mandated within the worker's jurisdiction], must include a comment made by the interpreting doctor on whether the administered bronchodilator had a significant effect on results.

In line with the 2022 ERS / ATS interpretative standards for lung function testing[3] changes in FEV_1 and FVC should be reported as a change relative to the GLI predicted value. This approach minimises the influence of sex and height on the magnitude of the bronchodilator response. A change >10% of the predicted value indicates a clinically relevant bronchodilator response.

Determination of a bronchodilator response

$$\text{Bronchodilator Response} = \frac{(\text{Post–bronchodilator value (l)} - \text{Pre–bronchodilator value (l)}) * 100}{\text{Predicted value (l)\#}}$$

A change of >10% is considered a significant BDR response.

#Predicted value should be determined using the appropriate GLI spirometry equation.

For example: A 28-year-old Caucasian male; 175 cm in height has a pre-bronchodilator FEV_1 4.41 L and a post-bronchodilator FEV_1 of 4.65 L. The predicted FEV_1 is 4.39 L (using the GLI Caucasian equation).

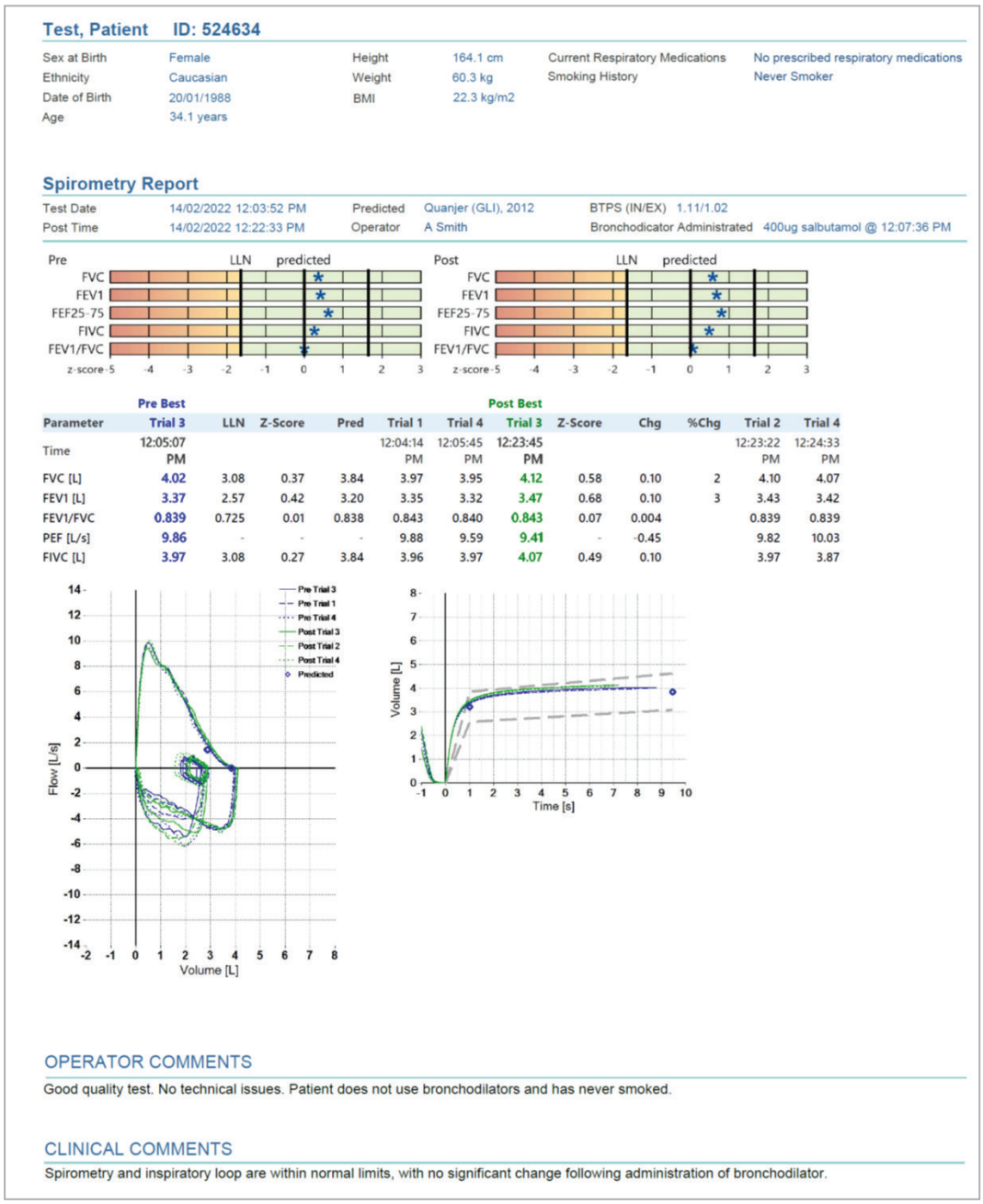
The bronchodilator response is calculated as $\frac{(4.65 - 4.41) * 100}{4.39} = 5.5\%$

Therefore, their BDR is reported as an increase of 5.5% of their predicted FEV_1 and is classified as not having a bronchodilator response.

Adapted from the 2022 ERS/ ATS Technical standard on interpretative strategies for routine lung function tests[3]

4.0 Reporting and interpretation

While typical patterns of abnormality can be recognised, spirometry used in isolation cannot specifically diagnose a particular condition. Doctors carrying out and reporting on the health assessment must be able to assess and comment on test quality. Spirometry reports and interpretations should be clear, concise, informative 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 interpretation of spirometry should align with the ERS / ATS interpretative standards for routine lung function tests. At the time of publication of these standards this was the 2022 ERS / ATS standards[3]. The sample Report provides an example of spirometry tests which meet these standards.



Test, Patient ID: 524634

Sex at Birth	Female	Height	164.1 cm	Current Respiratory Medications	No prescribed respiratory medications
Ethnicity	Caucasian	Weight	60.3 kg	Smoking History	Never Smoker
Date of Birth	20/01/1988	BMI	22.3 kg/m2		
Age	34.1 years				

Spirometry Report

Test Date	14/02/2022 12:03:52 PM	Predicted	Quanjer (GLI), 2012	BTPS (IN/EX)	1.11/1.02
Post Time	14/02/2022 12:22:33 PM	Operator	A Smith	Bronchodicator Administrated	400ug salbutamol @ 12:07:36 PM

Pre / Post — LLN / predicted — FVC, FEV1, FEF25-75, FIVC, FEV1/FVC — z-score -5 -4 -3 -2 -1 0 1 2 3

	Pre Best						Post Best					
Parameter	Trial 3	LLN	Z-Score	Pred	Trial 1	Trial 4	Trial 3	Z-Score	Chg	%Chg	Trial 2	Trial 4
Time	12:05:07 PM				12:04:14 PM	12:05:45 PM	12:23:45 PM				12:23:22 PM	12:24:33 PM
FVC [L]	4.02	3.08	0.37	3.84	3.97	3.95	4.12	0.58	0.10	2	4.10	4.07
FEV1 [L]	3.37	2.57	0.42	3.20	3.35	3.32	3.47	0.68	0.10	3	3.43	3.42
FEV1/FVC	0.839	0.725	0.01	0.838	0.843	0.840	0.843	0.07	0.004		0.839	0.839
PEF [L/s]	9.86	-	-	-	9.88	9.59	9.41	-	-0.45		9.82	10.03
FIVC [L]	3.97	3.08	0.27	3.84	3.96	3.97	4.07	0.49	0.10		3.97	3.87

Pre Trial 3, Pre Trial 1, Pre Trial 4, Post Trial 3, Post Trial 2, Post Trial 4, Predicted

Flow [L/s] — Volume [L]

Volume [L] — Time [s]

OPERATOR COMMENTS

Good quality test. No technical issues. Patient does not use bronchodilators and has never smoked.

CLINICAL COMMENTS

Spirometry and inspiratory loop are within normal limits, with no significant change following administration of bronchodilator.

Sample report: Pre and post - bronchodilator spirometry report.

4.1 Critique of the key parameters

4.1.1. 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.

4.1.2. FEV_1, FVC and the FEV_1/FVC ratio are the key parameters used for interpretation in their relation to:

4.1.2.1. reference equations.

4.1.2.2. previously performed results following:

- bronchodilator therapy in the assessment of bronchodilator responsiveness.
- an intervention or occupational exposure.

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 expressed as a percentage of the mean reference value (% predicted).

The reference ranges of the Global Lung Initiative (GLI)[4] must be utilised. The Global Lung Function Initiative for spirometry is a modern international dataset that includes a broad selection of healthy people from a range of ancestries. The Australian and New Zealand Society of Respiratory Science recommends that for Aboriginal and Torres Strait Islander workers the "GLI Other" category should be selected as the reference group[5]. The GLI spirometry dataset includes a North- and South-East Asian groups. However, not all countries within North- or South-East Asia were obtained as part of the GLI study. For the purposes of spirometry testing a regional approach should be adopted and workers assigned an ancestry category that they best identify with.

4.2 Typical patterns of respiratory abnormality

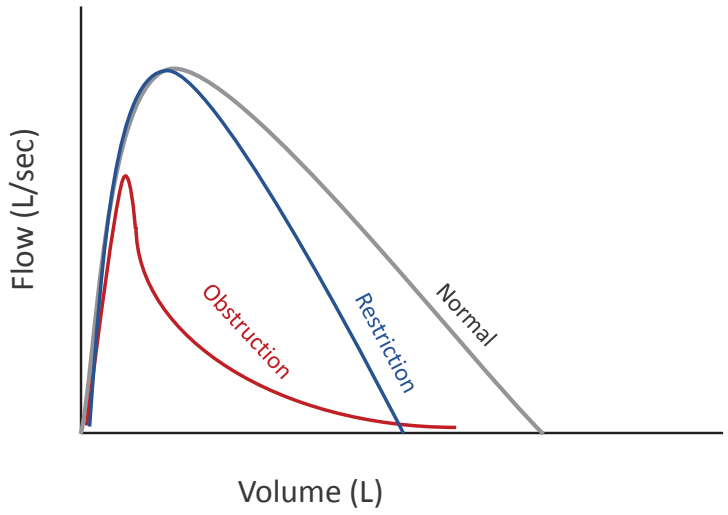


Figure 3. Visual representation of flow- volume curves showing normal spirometry and spirometry reflective of an obstructive and restrictive ventilatory abnormality.

Airflow obstruction

The worker is unable to expire quickly, i.e., airflow limitation, implying airway narrowing. This can be due to excess mucous 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. Results may include:

- FEV_1/FVC ratio below the lower limit of normal.
- FEV_1 may or may not be reduced 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. Results may include:

- FVC is below the lower limit of normal.
- the FEV_1/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. Results may include:

- the FEV_1/FVC ratio and FVC are below the lower limit of normal.
- FEV_1 % predicted is reduced.
- there is a distinct concave appearance of flow-volume curve with reduced volume.
- diagnosis requires confirmation from a specialist respiratory facility.

4.3 Bronchodilator responsiveness

Bronchial responsiveness to an inhaled bronchodilator involves integrated responses from the epithelium, nerves, mediators and bronchial smooth muscle. An individual's response to bronchodilator is assumed to test their underlying bronchial hyper-responsiveness, seen most commonly in people with asthma. Bronchodilator responsiveness may be performed when deemed to be clinically appropriate and must follow international standards as outlined in Section 3.3.

A clinically relevant bronchodilator response is defined >10% of the predicted value[3]. See breakout box in Section 3.3 for details.

4.4 Longitudinal monitoring

It is critical to evaluate an individual's lung function over time rather than an assessment of a single point in time compared against reference equations. This includes monitoring known abnormalities or assessing the effect of an intervention or occupational exposure.

A meaningful change over time must be greater than the inherent variability of the measure, which tends to be greater over weeks to months, than daily in biological controls.

Measures of FEV_1 or FVC, expressed in GLI % predicted, that decline by > 15% from baseline test over any period should be considered to be outside the normal longitudinal variability of spirometry[3,6]. A worked example is provided below for guidance in this calculation.

4.5 Interpretation of results

Spirometry results must be interpreted in line with any clinical guidelines mandated within the worker's jurisdiction. Otherwise, the most recent ATS/ERS Pulmonary Function testing Interpretation guidelines should be followed[3]. The doctor responsible for reporting on the health assessment must use the appropriate guidelines to determine the appropriate process for follow-up investigation and referral as clinically appropriate. A clinical interpretation of the spirometry assessment must be included in the spirometry report or linked clinical records [as mandated within the worker's jurisdiction].

These TSANZ Standards recommend that:

Spirometry of lower quality (ATS/ERS graded C or lower) is generally not be suitable for interpretation. Providers should consider retesting workers to ensure appropriate spirometry results are available.

Individuals should be referred to a respiratory and/or occupational physician as appropriate to the clinical findings if the following conditions are met:

- absolute FEV_1, forced vital capacity (FVC) or FEV_1/FVC is less than the lower limit of the normal (LLN) as determined using the GLI reference equations[3], or
- FEV_1 or FVC, expressed in GLI % predicted, declines by > 15% predicted from baseline test over any period[3].

Interpretation of changes in spirometry over time

The following worked example illustrates how to appropriately determine a change in spirometry over time in an individual. The use of appropriate alignment with robust predicted equations allows for changes with age to be accounted for. This example highlights that a significant decline in lung function can occur in individuals whose lung function remains within the normal range of the broader population.

A female worker, of Aboriginal ancestry, 170.5 cm tall enters the resource sector workforce at age 25.5 years. The Global Lung Function Initiative Spirometry 'Other' predictive equations are used as per ANZSRS recommendations[5].

Her lung function on entering the workforce was:

FEV_1	3.48 L	(103.1% predicted, LLN = 2.74 L)
FVC	3.94 L	(100.8% predicted, LLN = 3.16 L)
FEV_1/FVC	0.88	(101.7% predicted, LLN = 0.762)

Her spirometry is within normal limits. She does not report taking any respiratory medications.

At age 30.0 her respiratory health is reassessed. There are no reported symptoms, she does not report taking any respiratory medications and her lung function is:

FEV_1	3.31 L	(95.1% predicted, LLN = 2.65 L)
FVC	3.87 L	(99.4% predicted, LLN = 3.15 L)
FEV_1/FVC	0.81	(95.2% predicted, LLN = 0.750)

Her lung function remains within normal limits. Her change in FEV_1 (% predicted) over the five-year period is 8.0% (103.1% - 95.1%) and within acceptable limits.

At age 33.6 years she changes employers and undergoes a repeat assessment. She has no reported symptoms and does not report taking any respiratory medications. Her spirometry is:

FEV_1	2.85 L	(87.6% predicted, LLN = 2.599 L)
FVC	3.79 L	(98.0% predicted, LLN = 3.131 L)
FEV_1/FVC	0.75	(81.9% predicted, LLN = 0.741)

Her spirometry is within normal limits. Her change in lung function since entering the resource sector workforce at age 25 years is 15.5% (103.1% to 87.6% - after adjusting for age-related changes by using the GLI predicted equations). Based on the recommendations (above) her age-related longitudinal decline over the 8.1 years of employment exceeds 15.0%. She should be referred to an occupational and/or respiratory physician for further assessment.

5.0 Common causes of poor spirometry

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

Acceptable and repeatable manoeuvres will often superimpose with significant overlap when overlaid (e.g., Figure 4a). 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 reinstruct 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 4b).
- submaximal or variable efforts (e.g. Figure 4c).
- hesitation at the start of the expiration i.e. slow start (e.g. Figure 4d).
- cough in the first second of expiration (e.g. Figure 4e).
- submaximal inspiration or expiration (e.g. Figure 4f).
- mouth leaks.
- obstruction from tongue/teeth.
- poor posture, especially excessive leaning forward.
- lack of understanding/compliance.
- vocalisation.

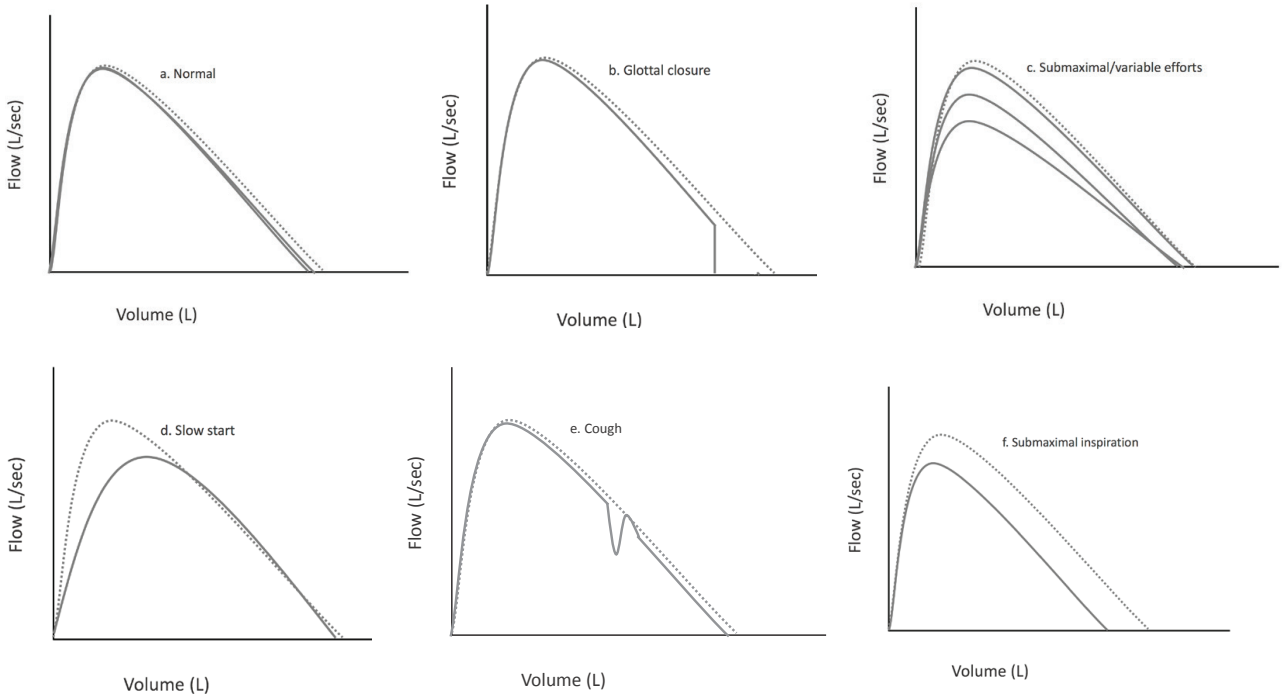


Figure 4. Visual representation of flow-volume curves showing normal (a) and poor (b to f) spirometry. Dotted line is expected normal curve.

6.0 References

1. Monash Centre for Occupational and Environmental Health. 2016. Review of Respiratory Component of the Coal Mine Workers' Health Scheme for the Queensland Department of Natural Resources and Mines. Accessed at https://www.rshq.qld.gov.au/__data/assets/pdf_file/0009/383940/monash-qcwp-final-report-2016.pdf

2. Graham BL, Steenbruggen I, Miller MR, Barjaktarevic IZ, Cooper BG, Hall GL, et al. Standardization of Spirometry 2019 Update. Am J Resp Crit Care Med. 2019;200(8):e70-e88.

3. Stanojevic S, Kaminsky DA, Miller M, Thompson B, Aliverti A, Barjaktarevic I, et al. ERS/ATS technical standard on interpretive strategies for routine lung function tests. Eur Respir J. 2021 Dec 23:2101499. doi: 10.1183/13993003.01499-2021

4. Quanjer PH, Stanojevic S, Cole TJ, Baur X, Hall GL, Culver BH, 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):1324-43.

5. Brazzale D, Hall G, Swanney MP. Reference values for spirometry and their use in test interpretation: A Position Statement from the Australian and New Zealand Society of Respiratory Science. Respirology. 2016 Oct;21(7):1201-9.

6. Redlich CA, Tarlo SM, Hankinson JL, Townsend MC, Eschenbacher WL, Von Essen SG, et al. Official American Thoracic Society technical standards: spirometry in the occupational setting. Am J Respir Crit Care Med 2014; 189: 983-993.

REVISION HISTORY			
1.	Version 1	2017	TSANZ Laboratory Accreditation and Quality Committee (LAQC)
2.	Version 2	March 2020	TSANZ Laboratory Accreditation and Quality Committee (LAQC)
3.	Version 3	March 2022	TSANZ Laboratory Accreditation and Quality Committee (LAQC)

AMENDMENTS	
1.	March 2020 – Update and reference to 2019 ATS/ERS Spirometry Standards including, but not limited to, terminology (entire document), spirometry repeatability criteria (Section 3.1), extrapolated volume criteria (Section 3.1).
2.	March 2020 – Include table specific to Mobile Spirometry Testing (Section 2.2).
3.	March 2020 – Include Revision History table.
4.	March 2020 – Formatting improvements to clarify mandatory audit requirements.
5.	November 2020 – Include RSHQ feedback.
6.	December 2020 – Removal of Algorithm for Interpretation of Spirometry In Resource Sector Workers.
7.	December 2020 – Definition of worker changed to resource sector worker from coal mine worker.
8.	December 2020 – DNRME is now Resources Safety and Health Queensland (RSHQ).
9.	December 2020 – Front page change Developed in Partnership With Queensland Government to Developed in Partnership with RSHQ.
10.	December 2020 – Removal of table 1 due to inconsistency with guidelines.
11.	June to December 2021 – Update to latest national and international standards; consultation and review with sector.

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