

## Spirometry (Adult) Respiratory Science

### Custodian/Review Officer:

Chief Allied Health Officer

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### Applicable To:

All Health Practitioners performing adult spirometry

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### Accreditation References:

EQulP and other criteria and standards

## 1. Purpose

This guideline provides recommendations regarding best practice to support high quality spirometry practice throughout Queensland Health facilities.

## 2. Scope

This guideline provides information for all health practitioners who perform adult spirometry as part of their clinical duties.

This guideline provides the minimum requirements for obtaining acceptable and repeatable pre- and post-bronchodilator (reversibility) spirometric data using both volume and flow-measuring devices.

## 3. Related documents

This guideline is primarily based on the following documents taken from the series “ATS/ERS Task Force: Standardisation of Lung Function Testing”

- General considerations for lung function testing (2005).<sup>1</sup>
- Standardisation of spirometry (2005).<sup>2</sup>

References from alternate sources of information have been identified in this document.

### Policy and Standard/s:

- [Informed Decision-making in Healthcare](#) (QH-POL-346:2011)<sup>3</sup>

### Procedures, Guidelines, Protocols

- [Australian Guidelines for the prevention and control of infection in healthcare](#) (CD33:2010)<sup>4</sup>
- 2005 American Thoracic Society and European Respiratory Society (ATS/ERS) guidelines<sup>1, 2</sup>



- Queensland Health Paediatric Spirometry Guideline

## Forms and templates

- Nil

## 4. Guideline for performing adult spirometry

### 4.1. Emergency Protocol

- Follow relevant Hospital and Health Service protocols or procedures in the event of an emergency.

### 4.2. Infection Control Procedures

- Testing patients with confirmed or suspected communicable diseases may pose a risk to staff and other patients due to potential cross-infection. See Appendix 1 for detailed infection control procedures.
- Adhere to relevant Hospital and Health Service infection control protocols or procedures at all times and in all facets of spirometry testing. Specific infection control procedures pertaining to spirometry testing are outlined in *Appendix 1: Infection Control Procedures*.
- [Australian Guidelines for the prevention and control of infection in healthcare \(CD33:2010\)](#)<sup>4</sup>

### 4.3. Gaining Consent

- Gain consent in accordance with Queensland Health's Informed Decision-making In Healthcare Policy<sup>3</sup>.

### 4.4. Identifying Indications and Contraindications for performing spirometry<sup>5</sup>

#### *Indications for performing spirometry*<sup>5</sup>

Spirometry has a variety of uses including:

- assisting with diagnostic evaluations
- monitoring of pulmonary function
- evaluating disability or impairment
- providing public health information.

For further indications refer to *Appendix 2: Purposes for performing spirometry*.

#### *Contraindications for performing spirometry*<sup>5</sup>

Some conditions may pose a relative danger to a patient or affect the validity of spirometry performance and results. These include, but are not limited to the following:

- unstable cardiovascular status, unstable angina, recent myocardial infarction (within one month), or pulmonary embolism
- haemoptysis of unknown origin
- recent pneumothorax
- thoracic, abdominal, or cerebral aneurysms
- recent thoracic, abdominal or eye surgery
- acute disorders such as nausea or vomiting
- severe respiratory distress
- physical limitations
- cognitive impairment, dementia.

#### 4.5. Facilities and equipment

##### *Testing Facilities*

- Ensure clearly defined rooms are available for spirometry testing, particularly for patients with confirmed or suspected communicable diseases, and immunocompromised patients. Specific infection control procedures pertaining to spirometry testing are outlined in *Appendix 1: Infection Control Procedures*.

##### *Spirometer*

There are two general types of spirometers: volume-displacement and flow-sensing spirometers (see *Appendix 3: General description of volume- and flow-sensing spirometers* for details).

When purchasing spirometers, ensure that:

- the spirometers meet the minimum ATS/ERS recommendations <sup>2</sup>
- the spirometers are capable of accumulating volume for  $\geq 15$ s and measuring volumes  $\geq 8$ L (BTPS) with an accuracy of  $\pm 3\%$  of reading or  $\pm 0.050$ L (whichever is greater) with flows between 0 and  $14 \text{ L}\cdot\text{s}^{-1}$
- the total resistance to air flow at  $14 \text{ L}\cdot\text{s}^{-1}$  is  $<1.5 \text{ cmH}_2\text{O}\cdot\text{L}^{-1}$  ( $0.15 \text{ kPa}\cdot\text{L}^{-1}\cdot\text{s}^{-1}$ ).

**Note:** For more detailed requirements refer to the ATS/ERS guidelines <sup>2</sup>.

##### *Other supplies:*

Assemble the following supplies:

- disposable/reusable supplies: mouthpieces, nose clips, flow sensors (pneumotachometers)
- infection control supplies: disposable in-line bacteria filters, gloves, gowns, masks, protective eyewear
- stadiometer for measuring height, scales for weight, tape measure for arm span
- computer/recorder supplies (depending on the type of spirometer used)



- barometer, thermometer and hygrometer, if not integrated into the equipment used. This equipment is used for correcting volumes to body temperature (i.e.37°C), ambient pressure, air saturated with water vapour (BTPS)
- validated 3L-volume calibration syringe
- for reversibility test: metered dose inhaler (MDI) and spacer, or small volume nebuliser with compressed gas source and disposable nebuliser mask/mouthpiece.

#### 4.6. Training requirements

All health professionals performing spirometry should as a minimum complete the Queensland Health Spirometry Training Program or another spirometry training to an equivalent standard <sup>6</sup>.

#### 4.7. Test Procedure

##### 4.7.1. Key measures and terminology

Abbreviation	Term	Definition/Explanation/Details
VC	Vital capacity, litres (L)	The volume change between the position of full inspiration and complete expiration <sup>7</sup>
FVC	Forced vital capacity, litres (L)	The maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration <sup>1</sup>
FEV <sub>1</sub>	Forced expiratory volume in one second, litres (L)	The maximal volume of air exhaled in the first second of a forced expiration from a position of full inspiration <sup>2</sup>
PEF	Peak expiratory flow litres per second (L.s <sup>-1</sup> ) or litres per minute (L.min <sup>-1</sup> )	The maximum expiratory flow achieved from a maximum forced expiration, starting without hesitation from a point of maximal lung inflation <sup>2</sup>
BPTS	Body pressure and temperature (saturated)	Body temperature (i.e.37°C), ambient pressure, saturated with water vapour <sup>1</sup>
Standard units		
L	Litres	
L/s	Litres per second	
L/min	Litres per minute	

##### 4.7.2. Preparing equipment and ensuring quality control

See *Appendix 4: Quality Control Procedures*.

##### *Preparing a spirometer:*

(as outlined in the ATS Pulmonary Function Laboratory Management Manual <sup>7</sup>)



- Assemble the components according to the manufacturer's instructions (i.e. tubing, connectors, flow-sensors, valves and adapters).
- Put in place a new in-line bacterial filter (if used), disposable mouthpiece or disinfected reusable mouthpiece for each patient.
- Turn on the system to ensure adequate warm up (refer to manufacturer's guidelines). Allow time for equilibration to room temperature for portable systems.
- Perform a validation check (calibration check) (For detailed procedures on performing validation and calibration see *Appendix 4: Quality Control Procedures*).
- Only perform spirometry at temperatures recommended by the equipment manufacturers.
- Document the environmental data from an accurate source representative of the laboratory prior to calibration.

**Note:** Environmental data includes internal spirometer temperature or ambient temperature, relative humidity (if applicable) and barometric pressure.

- Check for leaks daily when using volume-displacement spirometers. Leaks can be detected by applying constant pressure  $\geq 3.0$  cmH<sub>2</sub>O (0.3kPa) with the spirometer outlet occluded (at or including the mouthpiece). A volume loss of >30ml after 1 min indicates a leak and needs correcting. Refer to manufacturer's guidelines if a problem is detected.
- Check the flow-sensors for holes, clogging, channel plugging, or excess moisture daily. Refer to manufacturer's guidelines if a problem is detected.

#### *Validating the calibration of the spirometer:*

- A validation is the procedure used to check that the device is within calibration limits (e.g.  $\pm 3\%$  of true).
- Conduct daily validation checks according to manufacturer's instructions (see *Appendix 4: Quality Control* for details).<sup>2</sup>

**Note:** More frequent checks may be required where there is high patient throughput.<sup>2</sup>

#### 4.7.3. Preparing the patient

- Carry out infection control measures prior to testing, particularly hand washing for both patient and personnel performing spirometry.
- Document if the patient has withheld bronchodilator medications prior to testing.

**Note:** The use of bronchodilator is at the patient's discretion despite the recommendation to withhold before the test.

- Refer to section 4.7.6 *Assessing Bronchodilator Reversibility* for detailed instructions regarding withholding times.
- Confirm that the patient has<sup>1</sup>:
  - ceased smoking at least 1hr before testing
  - ceased alcohol consumption at least 4 hrs before testing

- refrained from performing vigorous exercise within 30min of testing
- refrained from eating a large meal within 2hrs of testing.
- Ensure the patient is wearing clothing that enables full chest and abdominal expansion (if possible loosen clothing).
- Assess patient for physical and developmental status to determine their ability to perform the test and/or if special arrangements are required e.g. if the patient has a tracheotomy.
- Engage an interpreter if required as per Queensland Health Language Services Policy<sup>8</sup>.
- Record relevant medical history that may assist in the interpretation/reporting of the spirometry. This may include the following.
  - Breathlessness
  - Cough
  - Sputum
  - Wheeze
  - Symptoms of asthma
  - Smoking history (years, packs/day, current status)
  - Known lung disease/chest injuries/operations
  - Work history
  - Occupational exposure to dust and respiratory irritants
- Record the type, dosage and time taken of any inhaled or oral medication that may alter lung function.
- Measure and record the patient's height (barefoot) in centimetres (cm) to the nearest cm, with feet together, heels against the wall, standing as tall and straight as possible and with the head in the Frankfort horizontal plane<sup>9</sup> (eyes level and looking ahead; for detailed explanation see *Appendix 5: Measurement of Stature*). Measure the patient's height using an accurate measuring device, such as a stadiometer.
- Patients with spinal deformities and for those who cannot stand, the measurement of arm span can be used as it closely approximates standing height<sup>10</sup>. Have the patient stretch their arms in opposite directions to attain the maximal distance between the tips of the middle fingers. Use the relevant formula below to estimate height.
  - For caucasian men:            Height = armspan÷1.03<sup>10</sup>
  - For caucasian women:        Height = armspan÷1.01<sup>10</sup>
- Measure and record the patient's weight in kilograms (kg) to the nearest 0.5kg with indoor clothing and without shoes. The weight is not required for most reference values but may be useful for interpretative reasons.
- Verify the patient's identity (full name and date of birth) and the procedure to be performed.



- Document the patient's ethnic origin, gender, date of birth and hospital identification (UR) number.
- Leave the patient's dentures in place unless they interfere with the testing procedure or the patient's ability to perform the procedure as required <sup>2</sup>.
- For safety reasons perform the test with the patient sitting comfortably in a chair with arms and without wheels. Ensure the patient is sitting in an upright position, legs uncrossed and both feet on the floor <sup>1</sup>.
- Clearly instruct the patient in the procedure prior to the commencement of each test and ensure that the patient understands all requirements of the test. . Allow ample opportunity for the patient to ask questions or receive clarification on the test and its requirements.

#### 4.7.4. Performing test procedure

***There are two methods for testing spirometry: Open-circuit and Closed-circuit.***

***In the open-circuit method the patient approaches the mouth piece after a complete inhalation to total lung capacity (TLC), whereas in the closed circuit method the patient inhales to TLC whilst firmly on the mouth piece and after several tidal volume (TV) breaths on the mouthpiece. Both methods are described below.***

1. Perform validation of the machine (see *Appendix 4: Quality Control Procedures* for details).
2. Introduce yourself to the patient, including your name and position title and establish rapport.
3. Verify the following information:
  - check for completed and signed doctor's request form, including indications and contraindications
  - identify patient by name, date of birth and hospital identification number
  - check for any contraindications to spirometry testing (see section *4.4 Indications and Contraindications for performing spirometry*)
  - record current medication that may alter lung function and a brief history (as outlined in section *4.7.6 Assessing bronchodilator reversibility*)
  - record height (cm) and weight (kg) measurements
  - record gender and ethnic origin
  - record testing position if not sitting and justification why test is performed in a non-sitting position.

#### *Performing the FVC and FEV<sub>1</sub> manoeuvre*

4. Explain and demonstrate the test manoeuvre to the patient, including:
  - Correct use of the mouthpiece and nose clip



- Correct posture with head slightly elevated
  - Position of the mouthpiece, including tight mouth seal over the mouthpiece.
  - Complete inhalation prior to FVC and FEV<sub>1</sub>
  - Rapid and complete exhalation with maximal force for FVC and FEV<sub>1</sub>.
5. Have the patient assume the correct sitting position i.e. upright posture, legs uncrossed and both feet flat on the floor.
  6. Activate the spirometer.
    - a) When using the open circuit method
      - Attach the nose clip and instruct patient to inhale completely and rapidly until their lungs are full, place mouthpiece in mouth and close lips tightly around the mouthpiece while holding their lungs full.
      - Instruct patient to exhale forcefully until no more air can be expelled.
    - b) When using the **closed circuit method**
      - Attach nose clip, place mouthpiece in mouth (or assist patient in positioning themselves on the mouthpiece) and instruct patient to close lips tightly around the mouthpiece and breathe quietly for no more than 5 breaths (i.e. relaxed, 'normal' tidal breathing).
      - Instruct patient to inhale completely and rapidly until their lungs are full.
      - With little or no pause at TLC (<1sec), instruct patient to exhale forcefully until no more air can be expired.
  7. Encourage the patient to maintain an upright posture (i.e. no bending forwards) during the manoeuvre.
  8. If a flow-volume “loop” is being performed (to measure forced inspiratory vital capacity) the patient will exhale rapidly and forcefully until end of test criteria are achieved, and then inhale as rapidly as possible back to TLC.
  9. Observe the patient at all times during the manoeuvre in case they become unsteady due to light-headedness or experience other adverse reactions, such as chest pain.
  10. Terminate the manoeuvre (using keyboard, mouse or special function keys as specified by the manufacturer) once the end of test criteria has been met (see *section 4.7.5 Determining acceptability and repeatability*).
  11. Repeat the instructions and manoeuvres for a minimum of three manoeuvres, more if necessary, coaching vigorously until end of test criteria are met; no more than eight manoeuvres are usually required.
  12. Terminate the test once the acceptability and repeatability criteria have been met (see *section 4.7.5 Determining acceptability and repeatability*).

### Performing the VC testing

1. Explain and demonstrate the test manoeuvre to the patient, including:
  - a) Correct use of the mouthpiece and nose clip



- b) Position of the mouthpiece, including tight mouth seal over the mouthpiece
- c) Correct posture with head slightly elevated
- d) Slow, complete and relatively constant flow inhalation for VC
- e) Slow, complete and relatively constant flow exhalation for VC
- f) Emphasis on complete filling and emptying of the lungs.

**Note:** If requested by the medical officer, it is recommended that the VC is performed before the FVC because of the potential for muscular fatigue and volume history effects <sup>2</sup>.

2. Have the patient assume correct posture and attach nose clip.
3. Activate the spirometer.
  - a) When using the open circuit method
    - Instruct the patient to inhale completely and rapidly until their lungs are full, place the mouthpiece in the mouth and close lips tightly around the mouthpiece while holding their lungs full.
    - Instruct patient to exhale slowly and completely until their lungs are empty.
  - b) When using the **closed circuit method**
    - Attach nose clip, place mouthpiece in mouth (or assist patient in positioning themselves on the mouthpiece) and instruct patient to close lips tightly around the mouthpiece and breathe quietly for no more than five breaths (i.e. relaxed, 'normal' tidal breathing).
    - Instruct the patient to inhale completely until their lungs are full and exhale slowly and completely until their lungs are empty. This provides a measure of expiratory vital capacity (EVC).
    - Alternatively, instruct the patient to exhale completely from end-inspiration on a tidal breath until their lungs are empty. This provides a measure of inspiratory vital capacity (IVC).
4. Encourage the patient to “keep going” until there is no volume change observed (see section 4.7.5 *Determining acceptability and repeatability*).
5. Observe the patient at all times during the manoeuvre in case they experience light-headedness or any other adverse reactions.
6. Terminate the manoeuvre (using keyboard, mouse or special function keys as specified by the manufacturer) once the end of test criteria have been met (see section 4.7.5 *Determining acceptability and repeatability*).
7. Repeat instructions and manoeuvres for a minimum of three manoeuvres coaching vigorously until end of test criteria are met; with a maximum of four attempts and a rest period of >1 minute between each manoeuvre.
8. Terminate test once acceptability and repeatability criteria are met (see section 4.7.5 *Determining acceptability and repeatability*).



#### 4.7.5. Determining acceptability and repeatability of FEV<sub>1</sub>, FVC and VC measurements

Clinically useful spirometry must be acceptable (i.e. meet the criteria that comprises a good quality manoeuvre) and repeatable (i.e. the two highest FEV<sub>1</sub>, FVC and VC from three acceptable manoeuvres are in close agreement).

*A spirometry is “acceptable” if the following are met:*

##### *Start of Test Criteria*

- begins from full inspiration
- has a rapid start of test, that is, the back extrapolated volume (BEV) is <5% of FVC or 0.15L, whichever is greater (see *Appendix 7: Determination of back-extrapolation volume*). If the manoeuvre has an obviously hesitant start then the trial should be terminated early to avoid unnecessary prolonged effort.

##### *Middle of Test Criteria*

- No obstruction, hesitation or artefact impeding the blow (see *Appendix 6: Examples of volume-time and flow-volume spirometry*) including:
  - a. Cough during the first second of exhalation
  - b. Glottic closure that influences the measurement
  - c. Early termination or cut-off
  - d. Effort that is not maximal throughout
  - e. Air leaks at mouth
  - f. Obstructed mouthpiece (due to tongue or teeth in front of the mouthpiece, or mouthpiece deformation due to biting).

##### *End of Test Criteria*

- Continuous maximal expiratory blow for ≥6 sec in duration
- A plateau in the volume-time curve (i.e. no change in volume (<0.025L) for a 1 second period)
- The patient cannot or should not continue to exhale <sup>2</sup>.



### *How to ensure repeatability between individual spiograms*

After three acceptable spiograms have been obtained, the following checks are used to assess for repeatability:

- The two largest values of FVC or VC must be within 0.150L of each other
- The two largest values of FEV<sub>1</sub> must be within 0.150L of each other
- For patients with an FVC or VC of  $\leq 1.0$ L the two largest FVC or VC and FEV<sub>1</sub> values must be within 0.100L of each other
- A minimum of three acceptable manoeuvres should be saved and utilised for analysis/interpretation.

### *Peak expiratory flow (PEF)*

During spirometry testing PEF is measured in conjunction with FEV<sub>1</sub> and FVC and can be used to indicate maximal patient effort.

**Note:** PEF can also be measured independently using a Peak Flow Meter. Refer to ATS/ERS guidelines (2005) <sup>2</sup>.

### *4.7.6. Assessing bronchodilator reversibility <sup>2</sup>*

Assessing bronchodilator reversibility is often performed as part of Spirometry. The choice of drug, dose and mode of delivery is a clinical decision made by the medical officer requesting the test, and dependent on the clinical question and clinical judgement.

#### *Patient Preparation*

- Bronchodilator medications should be withheld prior to testing if evidence of the presence or absence of reversible airflow limitation is required.
  - Short-acting bronchodilators ( $\beta$ -agonists or anticholinergics) should be withheld for 4 hrs.
  - Long-acting  $\beta$ -agonist bronchodilators, oral therapy with Aminophylline or slow release  $\beta$ -agonist should be withheld for 12hrs.
- If the aim of the test is to determine whether the patient's lung function can be improved with therapy in addition to their regular treatment, then regular medication as prescribed can be continued.
- All other preparation steps are outlined in section *4.7.3 Preparing the patient*.

#### *Administration of Bronchodilators*

- Regardless of which method is used, consideration of pulmonary deposition characteristics of the devices must be made so that appropriate and standardised dosages are delivered <sup>2</sup>.



- Salbutamol (Ventolin), the most commonly used bronchodilator, should be administered using metered dose inhalation of 400ug salbutamol (4x100ug metered doses at 30second intervals) via a valved spacer device <sup>2</sup>.
- Consult local Hospital and Health Service standing orders for bronchodilator administration for further guidelines.

### Test Procedure

- Perform spirometry according to *4.7.4 Performing Test Procedure*. This will provide a 'pre-bronchodilator' result.
- Administer the bronchodilator medication in the dose and method indicated for the test and according to hospital guidelines.
- Perform spirometry according to section 4.8.4 Performing Test Procedure 10 to 15 minutes following administration for short-acting  $\beta$ -agonists, and 30 minutes for short acting anti-cholinergic agents <sup>2</sup>. This will provide the 'post-bronchodilator' result.

### Acceptability and repeatability <sup>2</sup>

Ensure test acceptability and repeatability according to section *4.7.5 Determining acceptability and repeatability*.

#### 4.7.7. Interpretation of results <sup>11</sup>

A positive bronchodilator response is marked by significant reversibility. This is evident if there is:

- An increase in FEV<sub>1</sub> and/or FVC of  $\geq 12\%$  compared with pre-bronchodilator spirometry and
- $\geq 200\text{mL}$  increase in FEV<sub>1</sub> and/or FVC compared with a pre-bronchodilator spirometry.

#### 4.7.8. Reporting results <sup>2</sup>

- All volumes and flows are to be reported at BTPS conditions.
- FEV<sub>1</sub> and FVC should be reported in litres (L) to two decimal places.
- Peak flow should be reported in litres per second ( $\text{L}\cdot\text{s}^{-1}$ ) to two decimal places or in litres per minute ( $\text{L}\cdot\text{min}^{-1}$ ) with no decimal places.
- The largest VC from at least two acceptable and repeatable manoeuvres is reported.
- The largest FVC and largest FEV<sub>1</sub> from acceptable and repeatable manoeuvres are reported, even though the values may not come from the same manoeuvre.
- All other flows, if required by the requesting medical officer, are reported from the "best" test. The "best" test is defined as the manoeuvre with the largest sum of FVC and FEV<sub>1</sub>.
- If a single volume-time tracing or flow-volume curve is to be included in a final report, it should be the spirogram from the effort with the largest sum of FVC and FEV<sub>1</sub>.

- Expiratory and inspiratory flow-volume curves from different acceptable efforts may be combined to produce a flow-volume loop.
- A medical officer may request the reporting of other measurements (see section 5 *Definition of Terms*), in which case the largest value for all these measurements should be reported.
- The final report should include:
  - scientist's comments regarding acceptability and repeatability of the data
  - software version (if applicable)
  - date, time and results of most recent calibration
  - identification of reference values used.

**Note:** Test results that do not meet acceptability and repeatability criteria may still provide useful clinical information. It is important to make note of the reasons in the report, and advise to interpret with care.

#### 4.8. Quality Control Procedures

Quality control procedures specific to spirometry testing are detailed in *Appendix 4: Quality Control Procedures*. Daily validation (calibration checks), weekly biological control testing, and data analysis are the minimum quality control requirements.

### 5. Definition of Terms

Definitions of key terms are provided below.

Abbreviation	Term	Definition / Explanation / Details
VC	Vital capacity, litres (L)	The volume change between the position of full inspiration and complete expiration <sup>7</sup>
IVC	Inspiratory vital capacity, litres (L)	The maximal volume of air inhaled slowly from the point of maximal exhalation achieved by a slow expiration from end-tidal inspiration <sup>7</sup>
EVC	Expiratory vital capacity, litres (L)	The maximal volume of air exhaled slowly from the point of maximal inhalation <sup>7</sup>
FVC	Forced vital capacity, litres (L)	The maximal volume of air exhaled with maximally forced effort from a position of maximal inspiration <sup>1</sup>
FIVC	Forced Inspiratory Vital Capacity, litres (L)	The maximal volume of air inhaled with maximally forced effort from a position of maximal expiration <sup>7</sup>
FIFx%	Forced Inspiratory Flow, litres per second (L.s <sup>-1</sup> )	The flow measured during a forceful inspiration when x% of the FIVC has been inspired <sup>7</sup>
FEV <sub>1</sub>	Forced expiratory volume in one second, litres (L)	The maximal volume of air exhaled in the first second of a forced expiration from a position of



		full inspiration <sup>2</sup>
FEV <sub>t</sub>	Forced expiratory volume, litres (L)	The maximal volume of air exhaled with maximally forced effort in t seconds; 1 and 6 seconds are the most common <sup>7</sup>
FEV <sub>t</sub> /FVC Or FEV <sub>t</sub> /VC	Forced expiratory volume in t seconds to forced vital or vital capacity ratio	The ratio of FEV <sub>t</sub> to FVC or VC expressed as a percentage (FEV <sub>1</sub> is the most commonly used measure) <sup>7</sup>
FEF <sub>x</sub> %	Forced expiratory flow litres per second (L.s <sup>-1</sup> )	The flow measured during a forceful expiration when x% of the FVC has been exhaled; FEF <sub>25</sub> %, FEF <sub>50</sub> %, and FEF <sub>75</sub> % are commonly reported <sup>7</sup>
FEF <sub>25-75</sub> %	Forced mid-expiratory flow litres per second (L.s <sup>-1</sup> )	The average flow measured over the middle 50% of an FVC maneuver <sup>7</sup> . Also known as mid expiratory flow <sup>2</sup>
PEF	Peak expiratory flow litres per second (L.s <sup>-1</sup> ) or litres per minute (L.min <sup>-1</sup> )	The maximum expiratory flow achieved from a maximum forced expiration, starting without hesitation from a point of maximal lung inflation <sup>2</sup>
TLC	Total lung capacity, litres (L)	The volume of gas in the lungs after maximal inspiration, or the sum of all volume compartments <sup>12</sup>
TV	Tidal volume, litres (L)	The volume of gas inhaled or exhaled during the respiratory cycle (also known as VT) <sup>12</sup>
BTPS	Body temperature pressure and (saturated)	Body temperature (i.e.37°C), ambient pressure, air saturated with water vapour <sup>1</sup>
	Acceptability Criteria	Satisfactory start, middle and end of test conditions <sup>1</sup>
	Repeatability Criteria	Closeness of agreement between the results of successive measurements of the same item carried out, subject to all of the following conditions: same method, same observer, same instrument, same location, same conditions of use, and repeated over a short space of time <sup>1</sup>



## 6. Consultation

Key stakeholders (position and business area) who reviewed this version are:

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- Clinical Measurements Advisory Group (CMAG) for Clinical Education and Training.
- State-wide Clinical Measurements Network (SWCMN)
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- State-wide Respiratory Clinical Network (SWRCN), Deb C. Hill (Network Coordinator, State-wide Respiratory Clinical Network & Principal Project Officer, Clinical Networks Team, Patient Safety & Quality Improvement Service, Centre for Healthcare Improvement)

## 7. Guideline Revision and Approval History

Version No.	Modified by	Amendments authorised by	Approved by
1.0			Dane Enkera - Chair State-wide Clinical Measurements Network Brett Duce - Chair Clinical Measurements Advisory Group (for clinical education)

## 8. Appendices

### Appendix 1: Infection Control Procedures

The aim of infection control is to provide a better understanding of infections and their modes of transmission to staff. It is also important in maintaining a safe working environment for staff and patients to help prevent disease transmission during pulmonary function testing.

#### General Hygiene guidelines:

Poor hygiene practice not only increases patient morbidity but also increases patient mortality. Lung function testing equipment has the ability to spread or transmit blood borne and airborne pathogens (droplets and other particles containing microbes being released in the air) e.g. tuberculosis (TB), chicken pox respiratory syncytial virus (RSV), human immunodeficiency virus (HIV) and hepatitis. The majority of the patient population would not be affected but individuals who are immune-compromised are far more likely to develop complications <sup>4</sup>.

If an **active respiratory infection** has been identified in a patient then the test request should be confirmed with the requesting medical officer.

#### Transmission of pathogens <sup>1,7</sup>

Transmission of pathogens can occur via a number of different routes including: patient - staff, staff – patient, patient – patient, staff – staff, patient – equipment and staff – equipment.

ATS/ERS guidelines <sup>1</sup> define direct and indirect contact with regards to pulmonary function testing and transmission of pathogens as follows:

#### **Direct contact: (From person to person)**

There is the potential for transmission of upper respiratory disease, enteric infections, and blood-borne infections through direct contact. Although hepatitis and HIV transmission are unlikely via saliva, disease transmission is a possibility when there are open sores on the oral mucosa, bleeding gums, or haemoptysis. The most likely surfaces for contact are mouthpieces and the immediate proximal surfaces of valves or tubing.

#### **Indirect contact: (Via animate and inanimate objects)**

There is potential for transmission of TB, various viral infections, and possibly, opportunistic infections and nosocomial pneumonia through aerosol droplets. The most likely surfaces for possible contamination by this route are mouthpieces and proximal valves and tubing.





### Prevention and Precautions:

Standard precautions should be followed at all times. Disease prevention or cross contamination can be prevented by addressing the following issues regarding the source and the transmission of pathogens:

- ensuring a clean environment
- proper hand-washing techniques
- sterilisation and disinfection of equipment including valves and tubing
- use of in-line bacterial/viral filters safety mouthpieces
- personal protective equipment (e.g. gloves, gown, masks etc)
- isolation of infected patients (Source Isolation)
- precautions with testing patients with open sores or haemoptysis
- isolation of susceptible patients (Protective Isolation).

Hands should be washed between patients and immediately after direct handling of mouthpieces, tubing, breathing valves or the interior surfaces of equipment. Gloves should be worn at all times when handling contaminated equipment or where surfaces are suspected of holding pathogens which could be potentially transmitted. Gloves also offer another barrier of defence for staff with open cuts or sores which need to be covered to prevent contamination and or transmission of disease pathogens.

### Volume and flow-based spirometers:

Disposable in-line filters are an effective and less expensive method of preventing equipment contamination. In-line filters have been shown to remove microorganisms from the expiratory air stream and thus prevent their deposition as aerosol nuclei on spirometer surfaces. The use of in-line filters does not eliminate the need for regular cleaning and decontamination of lung function equipment. When using equipment with inspiratory and expiratory manoeuvres, in-line bacterial viral filters should be used and disposed of after every patient (single patient use).

### Closed circuit

A volume based spirometer in which a closed circuit technique has been used should be flushed between subjects with room air at least five times over the entire volume range of the spirometer to enhance clearance of droplet nuclei. The breathing tube or mouthpiece should be decontaminated or changed between patients.

### Open circuit

If the patient or subject only exhales into the spirometer, only the portion of the circuit through which re-breathing occurs must be decontaminated between patients. Alternatively a disposable sensor may be used and decontamination of sensors and mouthpieces can be avoided. A low resistance disposable one-way valve mouthpiece may be used to prevent inhalation from an open circuit. This mouthpiece needs to be disposed of between patients.



Common transmissible infectious diseases often seen in the Respiratory Laboratory include:

- Hepatitis B
- Hepatitis C
- Tuberculosis (TB)
- Human Immunodeficiency Virus (HIV)
- Pseudomonas cepacia
- Cytomegalovirus (CMV)
- Varicella Zoster Virus (VZV).

The ATS/ERS<sup>1</sup> recommends extra precautions are taken for patients with known transmissible infectious diseases.

- Reserve equipment for the sole purpose of testing infected patients.
- Test infected patients at the end of the day, allowing time for the equipment to be disassembled and disinfected.
- Test patients in their own rooms with adequate ventilation and appropriate protection for the technician. A negative air conditioned room is ideal for this situation and aids in the prevention of cross contamination.
- Place patients in a separate area apart from other patients, not in open waiting areas.
- Provide patients with surgical masks and instruct them to wear the masks. Provide patients with tissues and instructions on covering their mouth and nose when coughing or sneezing.

Environmental engineering controls such as ventilation, air filtration or ultraviolet decontamination of air should be used to help prevent disease transmission where spread is by droplet nuclei as seen in tuberculosis.

### Cleaning and Disinfecting Procedures

Mouthpieces, nose clips, and any other equipment coming into direct contact with mucosal surfaces should be disinfected, sterilized, or, if disposable, discarded after each use. Although the optimal frequency for disinfection or sterilization of tubing, valves, or manifolds has not been established, any equipment surface showing visible condensation from expired air should be disinfected or sterilised before reuse whenever the potential for cross contamination exists.

Manufacturer's recommendations regarding the cleaning and disinfection of equipment must be consulted in order not to cause damage with the wrong cleaning procedure. Heat sterilisation or cold sterilisation chemicals can damage flow sensors, tubes and or seals. Manufacturers should describe the recommended chemicals and concentrations as well as the PPE required by the staff undertaking the cleaning and disinfection procedure. However, Queensland Health infection control requirements supersede the manufacturer's recommendations so long as the equipment will not be damaged by these procedures.

All materials must be cleaned of debris before undergoing the disinfection process. There are four main categories of sterilization and disinfection; these are described below<sup>7</sup>.

## Heat

Heat is the universally employed and most reliable form of sterilization and is listed below in order of efficiency:

- Steam under pressure (autoclave)
- Steam at atmospheric pressure
- Boiling water
- Dry heat under pressure
- Dry heat at atmospheric pressure
- Water below boiling point (pasteurization).

## Cold liquid

Glutaraldehydes disinfect by interrupting metabolism and reproduction in microorganisms by binding to amino groups of proteins. These agents are bactericidal, tuberculocidal, fungicidal and viracidal in 10-30 minutes and sporicidal in 10hours. Many of these agents require special precautions. Comply with the material safety data of the product.

## Gas

Ethylene oxide (ETO) is the alkylating agent used extensively in gas sterilisation. However this agent is unsafe for the environment and requires stringent material preparation and monitoring.

## Other liquid disinfectants

Other disinfectant liquids include alcohol, quaternary ammonium compounds, acetic acid, formaldehyde, phenols, iodine, chlorine, and hydrogen peroxide.

1. Acetic acid solutions, quaternary ammonium compounds, and household bleach may be used for disinfecting respiratory equipment. However, studies have not been performed to verify the usefulness of these agents.
2. Alcohol and hydrogen peroxide may be used for skin cleaning and disinfection.



## Appendix 2: Purposes for performing spirometry

### Diagnostic indications

- evaluate symptoms, signs or abnormal laboratory tests – abnormal lab tests
- measure the effect of disease on pulmonary function – pulmonary dysfunction
- screen individuals at risk of having pulmonary disease – risk stratification
- assess pre-operative risk – pre-operative assessment
- assess prognosis – prognostic indicator

### Monitoring indications

- assess therapeutic intervention
- describe the course of diseases that affect lung function
- monitor people exposed to injurious agents
- monitor for adverse reactions to drugs with known pulmonary toxicity

### Disability/Impairment Evaluations

- assess patients as part of a rehabilitation program
- assess risks as part of an insurance evaluation
- assess individuals for legal reasons

### Public Health

- epidemiological surveys
- derivation of reference equations
- clinical research



## Appendix 3: General description of volume- and flow-sensing spirometers

For detailed information about specific models refer to the instruction and service manual for each spirometer. Refer to your local Hospital and Health Service protocols and procedures for details.

### Volume-displacement Spirometer: (e.g. wedge, rolling-seal)

The volume-displacement spirometer collects and directly measures the volume of expired air. There are two main types.

1. The **wedge-bellows spirometer** (Vitalograph) contains a collapsible bellows that unfolds in response to air being expired into it. It expands and contracts like a fan. One side of the bellows remains stationary, the other side moves with a pivotal motion around an axis through the fixed side. Displacement of the bellows by a volume of gas is translated to movement of a mechanical recording device. The chart paper moves at a fixed speed under the pen while a spirogram is traced.
2. The **dry rolling seal spirometer** consists of a chamber containing a piston which is attached to the inside of the chamber by a flexible seal. As air moves in and out of the spirometer the piston moves back and forwards. Displacement of the piston is translated to movement of a mechanical recording device.

### Flow-sensing Spirometer

The flow-sensing spirometer measures air flow rate directly. The volume is then derived electronically from the flow signal. There are several different types.

1. The **pneumotachometer** measures flow by using a *differential pressure flow sensor*, which consists of a tube containing a resistive element. The resistive element allows gas to flow through it, but causes a pressure drop. The pressure drop across the resistive element is measured by means of a sensitive pressure transducer, with pressure taps on either side of the element, and is proportional to the flow rate of gas as long as the flow is laminar (not turbulent). In some systems the resistive element is heated, which prevents accumulation of moisture from exhaled gas on the element.
2. The **ultrasonic flow sensor** measures flow using ultrasonic pulses travelling in opposite directions at an angle to the air flow. The speed at which the pulses travel is dependent on the air flow rate and direction, and can be determined from the time the pulses take to travel from one side to the other. The flow rate is thus determined from the pulse transit times.
3. The **hot-wire flow sensor** (anemometer, mass-flow sensor) contains a heated wire (or wires). As air flows past the wire it is cooled, with the degree of cooling dependent on the air flow rate. The air flow rate is proportional to the amount of electrical current required to keep the wire heated, which depends on the mass of air flowing over the wire.
4. The **rotating vane flow sensor** (turbine type) has a very light vane which spins when air flows past. The rotating vane interrupts the light path between a light source and photocell, causing pulses at the photocell. The air flow rate is proportional to frequency of these pulses.



## Appendix 4: Quality Control Procedures

Quality control must be conducted to ensure the precision and accuracy of the test equipment, test procedure and the results collected. It includes the regular maintenance and calibration of equipment and the regular testing of biological controls to validate testing equipment and test procedures. All results of quality control testing should be recorded and analysed so that any problems can be identified and rectified as soon as they arise. Quality control processes that conform to a “best practice model” are outlined below<sup>7</sup>.

### *Instrument maintenance*

Regular preventative maintenance must be performed by the operator to anticipate problems with the equipment before they occur. These should be done daily, weekly, monthly or yearly depending on the recommendation of the manufacturer.

- checking volume-displacement spirometers for leaks and linearity
- checking tubing for tears
- electrical safety

Corrective measures include unscheduled action required to correct the instrument failure and can be performed by the manufacturer, hospital bioengineer or the operating staff.

Maintenance logs must be kept and include dates and types of tasks conducted along with instructions on what action is to be taken if a problem is identified and needs to be rectified. At a minimum the following record should be kept:

- problem or troubleshooting log
- preventative maintenance list/log
- calibration log
- quality control log

New Instrumentation verification and validation must be performed on all new equipment before patient testing begins.

### *Instrument Calibration*

To have confidence in the data that is generated during spirometry testing, the spirometer must be regularly calibrated for volume, linearity and timing. Depending on the type of spirometer used, some or all of these parameters need regular validation.

#### Calibration syringe<sup>2</sup>

- The calibration syringe should be stored at the same temperature and humidity as the testing site, away from direct sunlight and heat sources. This is best achieved by storing the syringe close to the spirometer.
- A calibration syringe should be used to check the volume calibration of spirometers and must have an accuracy of  $\pm 15\text{mL}$  or 0.5% of the full scale, whichever is greater. For most spirometers the syringe volume required is 3L.



- A calibration syringe should be validated yearly to ensure accuracy. For specific details refer to the manufacturer's recommendations.
- A calibration syringe should be checked monthly for leaks by attempting to empty it with the outlet occluded. This should be performed at more than one volume.
- Perform inspection of adjustable or variable stops, if they exist, especially if the syringe has been dropped or damaged.
- Use of the syringe on a large number of machines distinguishes between instrument problems and problems with the syringe.

#### Procedure for validation (calibration checks)

- Volume validation ensures that the spirometer is within calibration limits (+/-3% of the true volume, usually 3L where a 3L syringe is used).
- Volume validation should be performed at least daily, or after every 10 patients in a busy service <sup>11</sup>.
- Recalibration may be indicated and BPTS correction factors updated if the temperature changes more than 50 C <sup>1</sup>.
- In-line bacterial-viral respiratory filters must be in place during the validation if they are used during testing <sup>6</sup>.
- For **volume-based** spirometers <sup>2</sup>
  - Check spirometer for leaks daily by applying a constant positive pressure of  $\geq 3.0 \text{ cmH}_2\text{O}$  (0.3 kPa) with the spirometer outlet occluded at the mouthpiece, preferably with the mouthpiece in place. A volume loss of 30ml after 1min indicates a leak and needs addressing.
  - Perform validation at least daily with a calibration syringe (the volume of the syringe will depend on the type of spirometer being used). Check manufacturer's guidelines for details.
  - A volume linearity check should be performed quarterly (1L increments with a calibrating syringe over entire volume range). The procedure is detailed in the ATS/ERS guidelines <sup>5</sup>. The check is considered accurate if the minimum volume accuracy requirements are met for all volumes tested, i.e. measured volume should be within  $\pm 3.5\%$  (this value includes the 0.5% syringe accuracy limit of the reading or 65ml, whichever is greater).
  - The following method can be used to check the linearity for each volume tested:
 
$$\% \text{ Error} = \frac{\text{Expected Volume} - \text{Measured Volume}}{\text{Expected Volume}} \times 100$$

Where:                      Expected volume = the actual volume of the syringe  
                                  Measured volume = the result recorded for the test
  - Perform timer checks **quarterly** for spirometers with mechanical recorder time scale. Using a stopwatch, an accuracy of 2% must be achieved.



- For **flow-based** spirometers <sup>2</sup>
  - Perform validation at least daily with a 3L syringe. Check manufacturer's guidelines for details.
  - A 3.00 L syringe should be injected at three different flow rates between 2 and 12 L.s-1 (with 3L injection times of ~6sec and < 0.5 sec); minimum volume accuracy should be within 3.5% at all flows.
  - For spirometers that use disposable flow sensors, a new unused sensor should be tested daily.
  - A flow linearity check of pneumotachs weekly ensures that minimum volume accuracy is met for the entire range of flows measured (low-, mid-, high-flows). If the spirometer meets volume accuracy requirements of  $\pm 3.5$  ml for all flow rates tested then it meets the requirements for linearity.

### Quality Control Analysis

Data from calibrations and other quality control procedures must be analysed regularly in order to be useful and contribute to quality assurance procedures. The results analysed must be obtained in a stable laboratory environment using the same calibration syringe, calibration procedure, biological standard or control material (eg. 3L syringe).

Biological Control is a healthy, non-smoking individual, usually a staff member, that is regularly tested and becomes the reference standard for the quality control program.

#### Biological control characterisation

Biological controls must initially be "characterised" according to the "gold standard" testing procedures before the data becomes the "reference standard". The biological control's lung function must be measured as accurately as possible under ideal conditions to determine a baseline value. All subsequent testing of the biological control is compared to this baseline value. Characterisation determines the variability of the biological control under the most ideal conditions.

Characterisation requires that:

- FEV<sub>1</sub>, VC, FVC volumes are measured according to ATS/ERS guidelines for acceptability and repeatability<sup>2</sup>.
- The subject is free of symptoms or known respiratory disease that may cause variability in lung function results that may affect lung function.
- Data is collected at least 10 times over a 1-2 week period under the above conditions to assess variability of the individual's data.
- The mean for each measured parameter becomes the reference standard or the "correct value".

#### Biological control data analysis

Day to day variations in physiological function of the biological control occur even under ideal testing conditions. The variability is used to set the "control limits for the test", and





allows identification of data that is “out of control”, and is determined by the following steps:

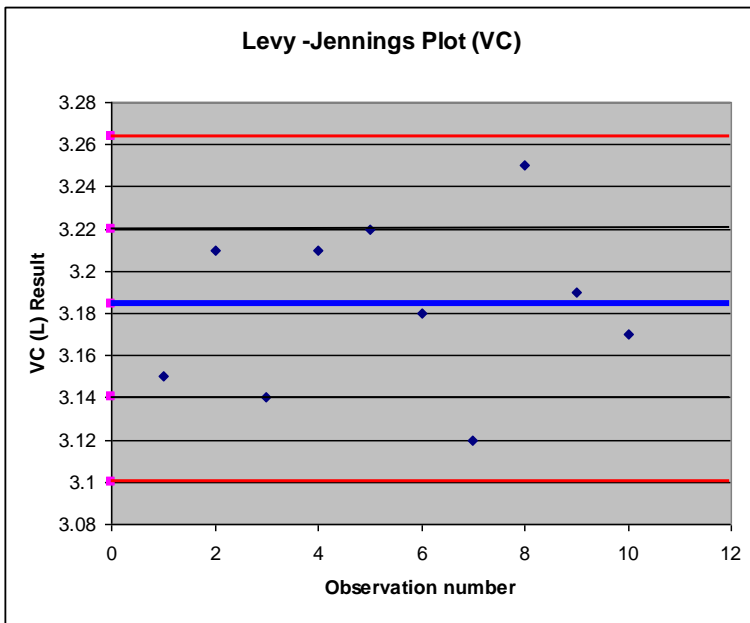
- record FEV<sub>1</sub>, FVC, VC for the 10 or more test manoeuvres performed
- for each parameter measured calculate mean and standard deviation (SD)
- the mean value during gold standard testing is the “correct value” for the biological control
- the standard deviation (SD) can now be used to set the control limits, where, mean  $\pm$  1.96 x SD gives a confidence interval of 95%, this means that approximately 95% of the values will be between  $\pm$  2SD of the mean.
- The biological control results, collected on a regular basis, can be plotted on a Levy-Jennings plot (see Graph 1) and interpreted using the Westgard rules. Westgard rules can be used to define specific limits for biological control results when compared with the “gold standard” testing results and to help determine if quality assurance responses need to be enacted, as follows <sup>7</sup>:
  - When one control observation exceeds the mean  $\pm$ 2 SD, a "warning" condition exists
  - When one control observation exceeds the mean  $\pm$ 3 SD, an "out of control" condition exists
  - When two consecutive control observations exceed  $\pm$ 2 SD, an "out of control" condition exists
  - When four consecutive control observations exceed the mean  $\pm$ 1 SD in the same direction, an "out of control" condition exists
  - When 10 consecutive control observations fall on the same side of the mean, an "out of control" condition exists
  - Generally, the following rules apply:
    - the  $\pm$ 2 SD limits are considered warning limits
    - values between 2 and 3 SD limits indicate an error and the procedure should be repeated
    - values beyond  $\pm$ 3 SD are considered unacceptable and the testing system should be evaluated.

#### Biological control testing procedure

- Routine biological control testing is performed weekly.
- Routine biological control testing is performed under the same condition as routine patient testing according to ATS/ERS guidelines <sup>2</sup>.
- Graph the biological control result on a Levy-Jennings Plot (see Graph 1), which has horizontal lines running across it to indicate the mean, as well as one, two and sometimes three standard deviations either side of the mean (derived from the characterisation of the biological control). These provide visual feedback of whether control values are “in” or “out of control”.



- Westgard rules are then used to determine if any quality assurance procedures need to be enacted.



Graph 1. Example of a Levy-Jennings plot showing the mean and one and two standard deviations derived from biological control characterisation. The observation points are VC results obtained from a biological control. In this example, no quality assurance procedures need to be enacted.

## Appendix 5: Measurement of Stature <sup>9</sup>

- The measurement is made using a stadiometer, leaving both hands free to position the subject whilst measuring height.
- Instruct patient to place heels together and stand as tall as possible with the heels, calf, buttocks and back preferably touching the stadiometer.
- Once the patient is in this position cup the angles of the mandible in both hands, tilt the patient's face so that the lower orbital margin (eye socket) is level with the external auditory meatus (Ear canal),
- This is the Frankfort Plane (solid horizontal line in Figure 1).
- Apply gentle upward traction to the head.
- If measuring a child, instruct the child to inhale deeply.
- Measure and record the height to the nearest centimetre in adults and 1 millimetre in children.

**Note:** Compared with subjects who are standing erect but unsupported this procedure can increase the apparent height by up to 5cm. It can also eliminate diurnal variation and improve the reproducibility, which is then less than 2mm.

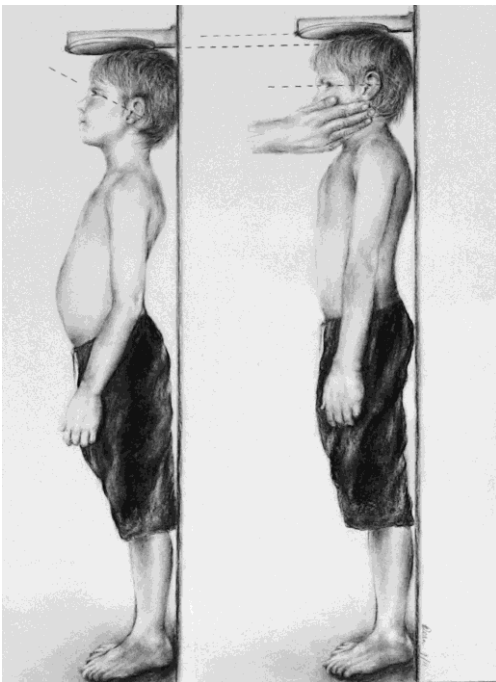


Figure1. Measurement of stature showing the effects of moving the head into the Frankfort plane (short dashed line at eye level) and then applying traction. The same method is also used for accurate height measurement in adults.

(Diagram supplied courtesy of Barry Dean, Queensland Children's Respiratory Centre, Royal Children's Hospital, Herston QLD, 4029)

Appendix 6: Examples of volume-time and flow-volume spirometry

Figure 1. Examples of unacceptable volume – time spirometry results compared with a good effort <sup>13</sup>

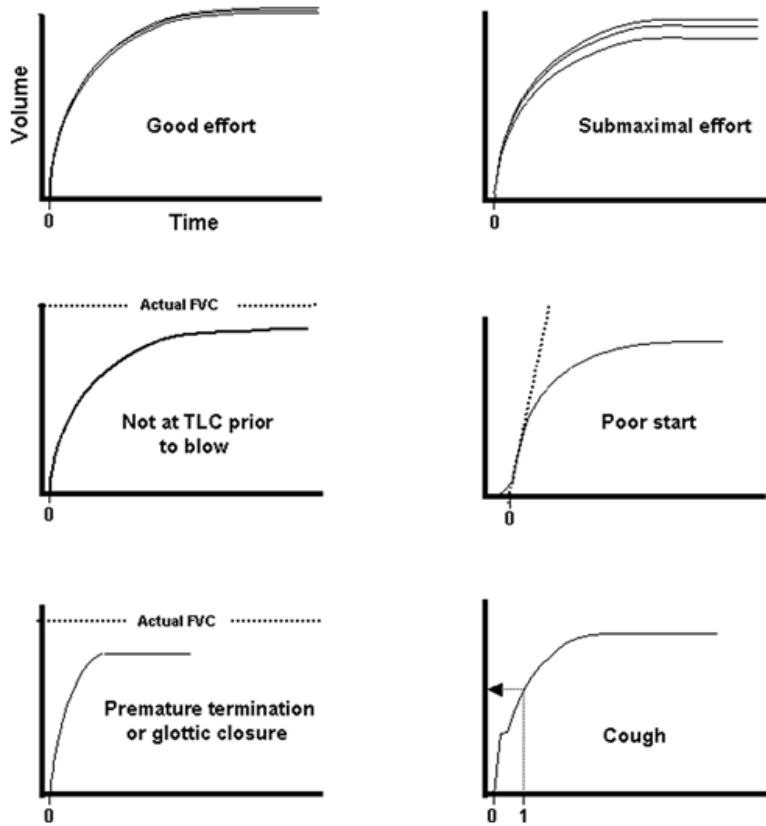
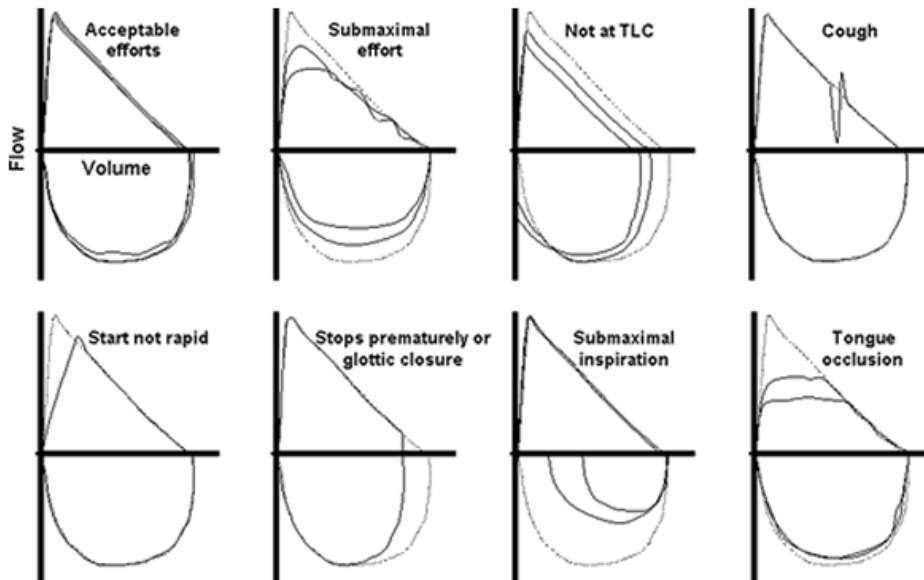


Figure 2. Examples of unacceptable flow-volume spirometry loops compared with an acceptable effort <sup>13</sup>



## Appendix 7: Determination of back-extrapolation volume

To determine the back-extrapolation volume a line is constructed through the steepest part of the volume–time curve (Figure 3). Where this line crosses the time axis is the new “time zero”, from which all time timed volumes (such as FEV<sub>1</sub>) are measured. The back-extrapolation volume is the volume on the spirogram at the new “time zero”. To render a spirogram acceptable the back extrapolation volume must be less than 5% of the FVC or 0.150 L, whichever is greater.

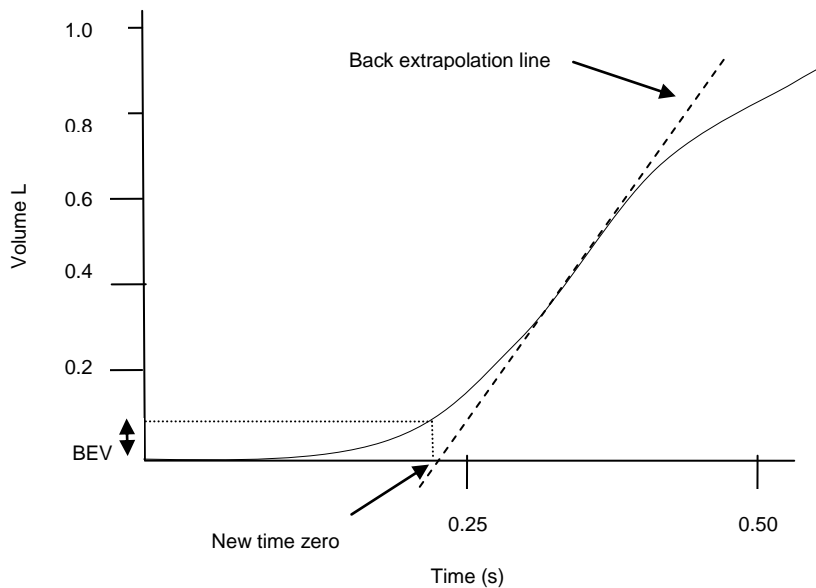


Figure 1 shows an expanded version of the early part of a volume-time spirogram, with a back extrapolation line through the steepest part of the curve to determine the new time zero at ~ 0.21sec. The back extrapolation volume is 0.09 L (determined by volume expired at new time zero). If the FVC is 4.18 L then EV is 2.1% FVC<sup>2, 14</sup>.

Most computerised systems provide immediate feedback on back-extrapolation volume and should be used by the operator to determine if this acceptability criterion has been met.



## 9. Suggested Readings and References

### 9.1. Suggested readings

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