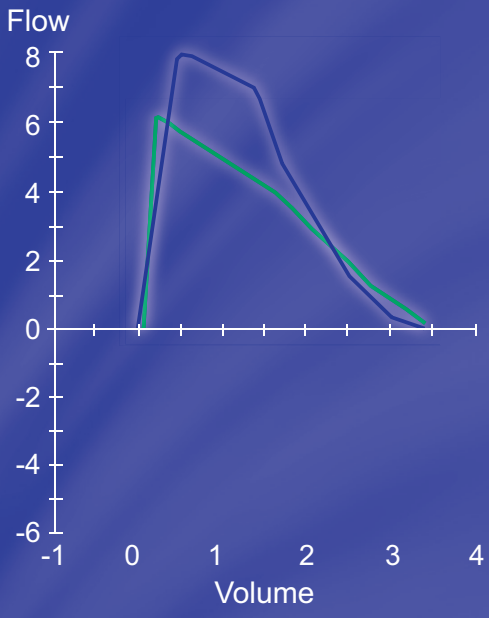
Guidelines for setting up a

spirometry service

Helping people to breathe easier



Normal Spirometry

Asthma

The Asthma and Respiratory Foundation of New Zealand (Inc.)
Te Taumatua Huango, Mate Ha o Aotearoa

Introduction

Spirometry is the most basic objective measurement of lung function. The results of well-performed spirometry give an indication of whether airflow and lung volume are appropriate for a patient's age, sex and height i.e. whether there is significant airflow obstruction (e.g. asthma or emphysema) or a significant reduction in lung volume (e.g. suggestive of a restrictive lung disease). Good quality spirometry requires a trained and experienced operator.

If spirometry results are to be clinically useful then they are criticially dependent on an accurately calibrated instrument capable of making the measurements precisely, an operator trained to recognise correct measurement techniques and a consistent and maximal effort by the patient.

There are many publications outlining good spirometry practice including Standards established by the American Thoracic Society (ATS Am J Respir Crit Care Med Vol 152, 1995), upon which New Zealand practice is based.

These guidelines were prepared by Maureen Swanney,
Scientific Director, Respiratory Physiology Laboratory
Christchurch Hospital.

Standardisation of Spirometry

There are four critical phases to performing quality spirometry

1. A full inspiration preceding the expiratory manoeuvre
2. A rapid forced expiration from a full lung
3. A complete exhalation until the lungs are completely empty
4. The manoeuvre is free from artefact i.e. cough, glottic closure etc.

Useful results depend on the elimination of variables other than those you are interested in i.e. variable inflation (alters expiratory force) and variable effort. Successful control of these other variables is gauged by reproducibility of the results. Accordingly, a minimum of three manoeuvres must be completed and the two best FEV_1s and FVCs must be at least within 200ml of each other. The first manoeuvre is often poor due to the learning required to do the test successfully so four manoeuvres are commonly required. It is recommended that no more than eight manoeuvres are performed at one session.

Lung volume and air flow depend on chest size. Therefore, reference values are determined from the patient's age, sex and height. It is essential that the reference values used are appropriate to the patient being tested. Your nearest respiratory laboratory can advise you on the choice of prediction equations. Although many spirometers already contain this information the 'pre-set' reference values may be inappropriate for our population in New Zealand.

Calibration and Quality Assurance

Calibration

Depending on the flow measuring technology, some spirometers require calibration each session. This requires a calibrated syringe (ideally 3 litre) with a leak free connection to the spirometer. The spirometer should be calibrated at two or three flows (high, mid and low flow) and the proceedure should include inspiratory and expiratory flows.

A number of spirometers do not allow calibration. This is a consequence of design. Inability to calibrate, however, does NOT absolve the operator from the need to validate the instrument.

Validation

ALL spirometers require regular validation. There are two aspects to this process.

1. **Validation** simply requires using your calibration syringe to make a vital capacity (VC) manoeuvre and verifying the result is accurate. Again this should be done at multiple flows to ensure linearity of response. Your local respiratory laboratory may be able to offer this service. The expected accuracy of volume calibration should be within 3% of the reference volume or 50 mls (whichever is greater). For example at 3 litres the volume of the spirometer should read within 2.91 – 3.09 L (at room temperature).

2. **Biological Controls** are an equally important component of validation. Spirometry should be regularly performed on a person (or better a group of people) who is a non-smoker, has no history of respiratory disease and stable lung function. These subjects should have their best values recorded along with the variability in their results. Tests should be performed at regular intervals, say once a week and a record of FEV_1 and FVC should be kept. Comparison of the measured values against their usual range allows immediate verification that the spirometer is measuring correctly. The advantage of biological control, over syringe control, is that the biological control tests assess all aspects of the instrument's function including operator technique.

Your local respiratory laboratory will be able to assist you to set up this biological control programme should help be needed. However, using yourself and staff as controls is the approach most usually employed.

Environmental Conditions

Gas volumes depend on pressure and temperature. Variation in pressure is not great and is rarely an issue. Air expands when heated, thus 2 litres of air in a room at 21°C will become 2.2 litres when inhaled into the lung at 37°C. Unless the spirometer has an internal temperature sensor, the operator must have access to accurate temperature recordings in the room in which spirometry is performed so the appropriate temperature correction of volume can be made. It is important that the measuring head of the spirometer is at room temperature before testing is commenced. A cold instrument from the car boot used in a warm room before the temperature of the instrument has equilibrated will generate erroneous results. Similarly a flow-head lying in the sun on a desk will be at a different temperature from the room and will also generate erroneous results.

Infection Control

Guidelines recommend that the staff member and the patient should wash their hands prior to testing.

It has become common practice to use bacterial/viral barrier filters on the flow-head of the spirometer. These filters lower the risk of cross infection between patients. These filters must be chosen carefully to ensure they do not compromise the measurements through imposing a resistance to airflow. ATS guidelines provide specifications for air flow resistance in a spirometer, the addition of a filter must not exceed this tolerance. An additional benefit of filter use is that the patient perceives their use to be an assurance that they are being protected from infection.

One brand of spirometer uses a disposable mouthpiece that isolates the exhaled breath from the spirometer. In this case there is no need for a barrier filter.

The disposable mouthpieces retail at approximately $3.50 each. Filters range in price from $3.50 to $5.00 each.

If filters are not used it is usual practice to wash/disinfect the flow-head of the spirometer between patients. You will need several flow-heads if you wish to test more than one patient within the time it takes for the flow-head to dry completely and be recalibrated.

There are other mouthpieces that contain a one-way valve preventing inspiration through the mouthpiece. These may be adequate but they prevent the measurement of inspiratory flow. Another consideration is that while the instruction is to exhale into the spirometer some people have difficulty comprehending the required manoeuvre and will attempt to inspire. Anecdotally, there have been incidents of inhaling the valve. They may be cheap but are not an ideal solution. In addition, these mouthpieces do not prevent exposure of the flow-head to moisture.

The outside of the spirometer should be wiped down between patients. Depending on the frequency of use it is recommended that the flow-head be cleaned periodically. It is ESSENTIAL that after any cleaning the spirometer's calibration is verified following reassembly.

Training personnel

Quality spirometry requires comprehensive training. The Australian and New Zealand Society of Respiratory Science in association with the Thoracic Society of Australia and New Zealand have developed a guideline for spirometry training courses preparatory to registering training courses available in Australia and New Zealand. Formal spirometry training courses are available in Auckland and Christchurch. Other centres in New Zealand will provide training, as the demand requires.

It is well documented that skill updating is a critical part of any quality assurance programme.

There is potential to do harm when performing spirometry and staff must understand the risks and how to deal with emergencies should they arise.

Core content of suitable training courses includes comprehensive training in:

- Knowledge of internationally accepted guidelines.
- Practical knowledge of how to perform quality spirometry.
- Principles of measurement and the importance of quality control.
- Infection control.
- Knowledge of indications for testing.
- Knowledge of contraindications to testing.
- Basic interpretation skills, whether for diagnosis, research or disability assessment.

Interpretation algorithm

Obstructive or Restrictive?

1. Examine reported data for accuracy and reproducibility and refer to additional technical comments on test performance.
2. Determine if the FEV_1/FVC ratio is normal or reduced (below the reference range).
3. If the ratio is normal or high, examine the vital capacity, if FVC is low the result suggests a restrictive pattern and referral for lung volume testing is recommended. Otherwise you can be confident the result is within the reference range.
4. If the FEV_1 is low (below the reference range), obstructive lung disease is present. The severity of obstruction is assessed using the % predicted FEV_1.

Figure 2. Restrictive pattern. FEV_1/FVC ratio elevated. Reduced FVC at 66 per cent reference value i.e. below the 95% C. I.

Age: 49 Height (cm): 167 Weight (kg): 146.5 BMI: 52.53 Gender: male

	Ref	Pre Meas	Pre %Ref	Post Meas	Post % Chg	CI	LLN
FEV_1 (L)	3.24	2.27	70			1.00	
FVC (L)	4.30	**2.85	**66			1.36	
FEV_1/FVC %	75	80					
PEF (L/sec)	8.05	7.59	94			3.87	
FEF25-75 (L/sec)	4.09	2.72	67			2.67	
FET100% (sec)		14.86					
FEV_6	4.23	2.69	64				3.43
FEV_1/FEV_6	80	84					72

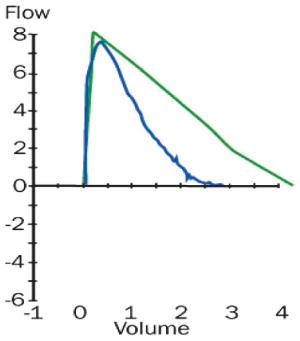
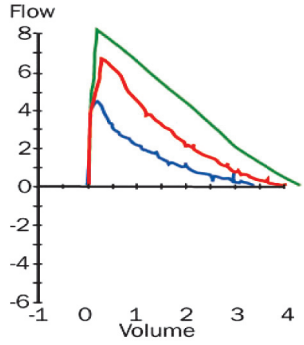


Figure 3. Obstructive pattern with clinically significant bronchodilator response. FEV_1 percentage reference shows an improvement from 64 to 92 per cent

Age: 59 Height (cm): 172 Weight (kg): 92.0 BMI: 31.10 Gender: male

	Ref	Pre Meas	Pre %Ref	Post Meas	Post % Chg	CI	LLN
FEV_1 (L)	3.11	**2.00	**64	2.85	42	1.00	
FVC (L)	4.35	3.40	78	4.10	21	1.36	
FEV_1/FVC %	72	59		69			
PEF (L/sec)	8.17	4.45	54	6.81	53	3.87	
FEF25-75 (L/sec)	4.06	**1.23	**30	2.24	82	2.67	
FET100% (sec)		7.46		10.62	42		
FEV_6	4.22	3.40	81	3.97	17		3.34
FEV_1/FEV_6	79	59		72			70



Severity of Obstruction?

The severity can be categorised using the TSANZ criteria

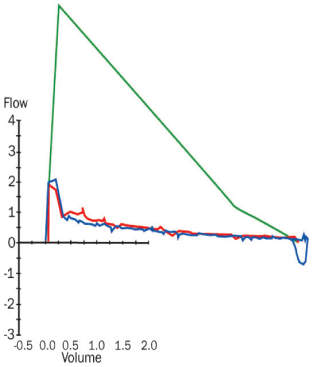
Mild Obstruction	% Pred FEV_1 > 60%
Moderate Obstruction	% Pred FEV_1 < 60 and > 40%
Severe Obstruction	% Pred FEV_1 < 40%

Figure 4. Severe obstructive pattern with no bronchodilator response. FEV_1/FVC ratio 22 per cent. FEV_1 36 per cent of reference value. Note expiratory time of 20 seconds

Age: 78 Height (cm): 175 Weight (kg): 77 BMI: 25.14
Gender: male

	Ref	Pre Meas	Pre %Ref	Post Meas	Post % Chg	CI	LLN
FEV_1 (L)	2.59	**0.93	**36	**0.94	1	1.00	
FVC (L)	4.02	4.20	104	4.06	-3	1.36	
FEV_1/FVC %	67	22		23			
PEF (L/sec)	7.75	**2.58	*33	**2.23	-13	3.87	
FEF25-75 (L/sec)	3.57	**0.28	**8	**0.29	4	2.67	
FET100% (sec)		20.64		20.56	-0		
FEV_6	3.67	2.51	68	2.62	4		2.79
FEV_1/FEV_6	77	37		36			68

Green = REF; blue = PRE; red = POST



Reversibility testing

1. Confirm the patient has withheld medication appropriately prior to testing reversibility eg. salbutamol for 6 hours, salmeterol for 24 hours.
2. Measure baseline spirometry in usual way
3. Administer bronchodilator medication (MDI and spacer or nebuliser).
4. Wait the required time for peak efficacy.
   - 15-20 minutes for salbutamol.
   - 25-30 minutes for ipratropium bromide or salbutamol with ipratropium bromide.
5. Perform post-bronchodilator spirometry as for baseline test.

Significant reversibility is defined (TSANZ) as greater than **12% improvement in FEV_1 and/or an increase of 200 ml** (200 ml is the natural variability of the test). Note that FVC can also rise significantly such that FEV_1/FVC can fall despite good bronchodilation. Do not use $FEF_{25-75\%}$ for assessing reversibility.

Reversibility may also be assessed measuring spirometry before and after a one-month trial of inhaled glucocorticosteroids or 2 weeks of oral prednisone with spirometry on the last day of the trial.

- Knowledge of bronchodilators and reversibility testing.
- Choosing appropriate reference equations.
- Trouble-shooting skills.
- Choosing appropriate and reliable equipment.

Competency training will probably become mandatory and it will become important to demonstrate competency on an ongoing basis. There is a professional responsibility to be competent and this will increasingly be an issue for accreditation of services, insurance and ACC claims and the responsibility to detect early disease.

Interpretation of spirometry

Spirometers are able to produce a long list of indices in their reports. The frequency of introducing a false negative result increases with the number of indices reported. A simple regimen for interpreting data is to limit your inquiry to three parameters *viz*. FEV_1/FVC, FEV_1 and FVC, plus careful inspection of the accompanying flow-volume or volume-time curves. The following is a simple guide to interpreting spirometry.

Figure 1. Normal spirometry (see cover diagram)

Age: 46 Height (cm): 166 Weight (kg): 57.0 BMI: 20.69 Gender: female

	Ref	**Pre Meas**	**Pre %Ref**	**Post Meas**	**Post % Chg**	**CI**	**LLN**
FEV_1 (L)	2.70	2.94	109			0.84	
FVC (L)	3.52	3.63	103			0.99	
FEV_1/FVC %	76	81					
PEF (L/sec)	6.20	8.30	134			2.84	
FEF25-75 (L/sec)	3.79	4.47	118			1.82	
FET100% (sec)		15.96					
FEV_6	3.69	3.74	94				2.98
FEV_1/FEV_6	83	85					74

Choosing a spirometer

While cost is always an important consideration when choosing equipment, the ability of the instrument to deliver quality results should be more important.

Key features of a spirometer suitable for diagnostic testing

- It must have a comprehensive manual, which describes features, usage and maintenance.
- It must have a real-time display of the flow-volume graphic visible during testing to allow monitoring and coaching for the manoeuvre. The real-time display must be of adequate size to allow comment on the acceptability of the test.
- It must be able to record for a sufficient time to enable the complete manoeuvre to be recorded. It could take more than 15 secs for a COPD patient to exhale completely.
- It must allow the operator to verify and choose the best test data.
- It must allow the operator to select the appropriate reference values.
- The printed report should be of suitable size and contain the information required including last calibration/verification date, source of predicted values, patient demographics, date of test and the desired measurements. It should be possible to include a flow-volume graphic in the report.
- Must have software feedback on the quality of each test.
- Spirometry indices must be corrected to and reported at BTPS conditions.
- It must be easy to calibrate (if appropriate) and validate the instrument.

In addition the supplier of the instrument must provide

- Training in the use of the equipment after purchasing (this training does not replace a spirometry training course).
- Reliable access to servicing from the manufacturer through their representatives.

The spirometers listed overleaf satisfy most of these criteria. The list does not cover all available instruments either because they are not recommended or they are new to the market and we are unaware of them. The majority of spirometers at the lower end of the market are intended for monitoring purposes only and are not designed for diagnostic purposes. Monitoring spirometers are useful for single patient use but have limitations for diagnostic use.

All the spirometers listed can be linked into a PC for data storage. The prices quoted are for a single instrument. Bulk purchases will attract a discount.

Spirometer	Manufacturer	Price	Distributor
SpiroPro (Printer not included)	SensorMedics/ Jaegar	$4,000.00 + GST	CARE Medical 0800 333 444 sales@caremed.co.nz
Flowscreen (Integrated ticket thermal printer)	Jaegar	$5,800.00 + GST	
Easy One (may be downloaded to any printer) Optional software	ndd	$3,850.00 + GST $750.00 + GST	McLaren Medical Ltd 0800 626 334 handfield@mcmed.co.nz
Spirolab II (Built in printer, Winspiro software CD included)	MIR	$4,200.00 + GST	McLaren Medical Ltd 0800 626 334 handfield@mcmed.co.nz
Microloop (SPIDA windows software included Printer not included)	Micro Medical	$3,760.00 + GST	Cass Distributors 0800 122 277 info@cass.co.nz
Microlab (Built in printer, SPIDA software not included)	Micro Medical	$4,385.00 + GST	
Microlab (Built in printer, SPIDA software included)	Micro Medical	$5,370.00 + GST	

Readings

Pocket Guide to Spirometry. David P Johns and Rob Pierce. McGraw-Hill Australia Pty Ltd. ISBN 0 074 71331 0.

Medical Section of the American Lung Association. 1994. Standardization of spirometry: 1994 update. Am. J. Respir. Crit. Care Med. 152:1107-1136.

G.T. Ferguson, P.L. Enright, A.S. Buist, and M.W. Higgins. 2000. Office spirometry for lung health assessment in adults: A consensus statement from the national lung health education program. Chest 117:1146-1161.

Medical Section of the American Lung Association. 1991. Lung function testing: selection of reference values and interpretative strategies. Am. Rev. Respir. Dis. 144:1202-1218.

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Canterbury Asthma Society
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Eastern Bay of Plenty Asthma and CORD Support Group
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