



A Guide to Performing Quality Assured Diagnostic Spirometry

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Foreword

Spirometry is an essential investigation for diagnosis and severity assessment in people with COPD and other respiratory conditions.

Most COPD is undetected: around 835,000 people have been diagnosed in England, while 2.2 million people are living with COPD but do not know they have the condition. Over half those with moderate and severe disease and the vast majority of those with mild disease are undiagnosed.

Failure to diagnose matters because decline in lung function is faster in the earlier stages of COPD and undiagnosed patients do not receive the treatment that we know makes a big difference to outcomes.

At the same time evidence suggests that around a quarter of people on general practice COPD registers do not meet the diagnostic criteria for COPD. They may therefore be receiving inappropriate and expensive therapies. This level of mis-diagnosis occurs because much of the diagnostic spirometry currently performed fails to meet the essential quality standards.

Spirometry is used in conjunction with clinical assessment for diagnosis of lung disease, but also for case-finding and disease monitoring. For case-finding, clinicians may use rapid *non-diagnostic* spirometry to exclude people who have symptoms but normal lung function - those with abnormal results then proceed to *diagnostic* spirometry. FEV₁ monitoring is also used by GPs to monitor changes in air flow obstruction over time as required by QOF. However, when used for diagnosis of disease spirometry must be quality assured and should only be performed to an approved standard – without this assurance the validity of the diagnosis cannot be relied on.

This step by step guide shows how high quality diagnostic spirometry can be delivered in primary care and elsewhere. It provides a clear outline covering operator competency, calibration and cleaning, preparation of the patient, operation of the equipment, interpretation of results and quality assurance.

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1 Introduction

Spirometry is the recommended objective test performed to identify abnormalities in lung volumes and air flow¹. It is used in conjunction with physical assessment, history taking, blood tests and x-rays, to exclude or confirm particular types of lung disease, enabling timely diagnosis and treatment. To be valid spirometry that is used for diagnosis must be quality-assured and should only be performed by people who have been trained and assessed to ARTP² or equivalent standards by recognised training bodies in the performance and interpretation of spirometry. Without this overall quality assurance the accuracy of the diagnosis cannot be relied on.

Spirometry is the standardised measurement of a forced expiration (and sometimes inspiration) into a calibrated measuring device or “spirometer”. Spirometers are usually flow-measuring devices that use a variety of physical technologies (turbine, pneumotachograph, ultrasonic) to measure flow and then calculate volume with respect to time. There are several makes of equipment and all spirometers need as a minimum to meet the standards of measuring and recording as specified in international guidelines.

Equipment requirements and standards

- A spirometer which meets the ISO standard 26782³
- One-way mouthpieces and nose clips
- Bacterial and viral filters (as indicated in selected patients)
- Height measure and weighing scales – calibrated according to manufacturer’s instructions.
- Nebuliser or single patient use volumatics (for post bronchodilator spirometry and reversibility testing)
- Single-patient use mask/mouthpiece for nebuliser
- Short acting bronchodilators as per guidelines (see below)

Calibration

Calibration of spirometry test equipment should be performed using a 3 litre syringe following the manufacturer's recommended procedures. For the device to be within calibration limits it must read +/- 3% of true³. Calibration should be *verified* prior to every clinic/session or after every 10th patient (whichever comes first). A calibration log should be maintained.

The standard⁴:

- Use an annually certificated calibration/verification 3L syringe - this must have an accuracy of +15ml
- Document calibration/verification results consistently, including a simple log of problems as they arise
- Document all repairs and computer software updates related to each specific Spirometer.

Cleaning

Any necessary cleaning and maintenance processes should be carried out on a regular basis according to manufacturer's instructions⁴ with reference to local guidelines and protocols.

2 Performing Spirometry

Step 1: Before day of test - determine type of spirometry required

1. Base-line spirometry

Investigative: to investigate lung function where diagnosis has not been established

2. Post bronchodilator spirometry

Investigative: to diagnose obstructive conditions where baseline spirometry shows obstructive pattern

Monitoring: to monitor clinical progress in diagnosed COPD and asthma

3. Reversibility testing

Reversibility testing may help to differentiate asthma from COPD but is rarely required. It can be unreliable and differentiation is usually based on clinical features.

Step 2: Pre-test advice to patient^{4,5,6} – will depend on purpose of the spirometry

Investigative To establish diagnosis	Monitoring Existing conditions	Reversibility testing
Spirometry tests required: <ul style="list-style-type: none"> ● Base-line test ● If obstructive base-line picture proceed to post-bronchodilator test (see below for standard) 	Spirometry tests required: <ul style="list-style-type: none"> ● Post-bronchodilator test (see below for standard) 	Spirometry tests required: <ul style="list-style-type: none"> ● Base-line test ● Post-bronchodilator test (see below for standard)
Before the test STOP: <ul style="list-style-type: none"> ● Short acting bronchodilators for 4 hours ● Long acting beta 2 agonist bronchodilators for 8 hours ● Long acting anticholinergic bronchodilators for 36 hours Before the test CONTINUE <ul style="list-style-type: none"> ● Inhaled and oral steroids 	Before the test CONTINUE <ul style="list-style-type: none"> ● All usual inhaled therapy 	Before the test STOP <ul style="list-style-type: none"> ● Short acting bronchodilators for 4 hours ● Long acting beta 2 agonist bronchodilators for 8 hours ● Long acting anticholinergic bronchodilators for 36 hours Before the test CONTINUE <ul style="list-style-type: none"> ● Inhaled and oral steroids
Ask the patient to avoid: <ul style="list-style-type: none"> ● Smoking for at least 24 hours before the test ● Eating a large meal before the test ● Vigorous exercise before the test ● Wearing tight clothing 		
Ask the patient to bring existing inhalers to the appointment		
Check if any contra-indications (see below) or allergies and ensure patient has prescription for bronchodilator		

On the day of the spirometry test

Step 1:

Assess the patient for contra-indications to spirometry⁷.

It should not be assumed that these have already been assessed by the referrer, and for some patients a degree of clinical judgement will be required in interpreting contraindications.

Absolute

- Active infection e.g. AFB positive TB until treated for 2 weeks
- Conditions that may be cause serious consequences if aggravated by forced expiration e.g. dissecting / unstable aortic aneurysm, current pneumothorax, recent surgery including ophthalmic, thoracic abdominal or neurosurgery

Relative

- Suspected respiratory infection in the last 4-6 weeks
- Undiagnosed chest symptoms e.g. haemoptysis
- Any condition which may be aggravated by forced expiration
e.g. history of prior pneumothorax; unstable vascular status such as recent (within 1 month) myocardial infarction, uncontrolled hypertension or pulmonary embolism or history of haemorrhagic event (stroke); previous thoracic, abdominal or eye surgery
- If the patient is too unwell to perform forced expiration
- Communication problems such as learning disability or confusion

Step 2:

Measure the patient's height and weight. Enter required values into the spirometer

The standard^{4,5}:

- Height – measured without shoes. If unable to measure height use arm span instead.
- Age and gender
- Ethnicity – this should be entered as per spirometer manufacturer's instructions.

Step 3:

Explain and demonstrate the procedure to the patient so that they understand what is required of them, and why it is important to perform each manoeuvre as best they can. You will need to explain that there will be two different blows performed for this procedure; the Vital Capacity (**VC**) and the Forced Vital Capacity (**FVC**), and that they will need to perform each type of blow on several occasions.

Step 4:

Prepare patient and equipment to perform the **baseline VC**.
Apply nose clip.

The standard^{4,5}:

- Patient is sitting comfortably
- A minimum of three acceptable VC manoeuvres must be obtained.
- Repeatability criteria are met when there is no more than 100mls ideally (and certainly no more than 150mls in the occasional highly variable patient) between each blow. Some spirometers will inform the user when this has been achieved.
- Verbally encourage patient to continue to exhale as long as possible
- Observe both patient and the time volume curve as each VC is performed to ensure they:
 - Breathe in to maximal inspiration
 - Do not obstruct the mouthpiece with their teeth or tongue.
 - There are no leaks from the mouthpiece
 - Remove false teeth if loose
- Usually this will be achieved within no more than four VC manoeuvres
- If the patient is unable to achieve the quality criteria, record why this has not been possible. Another appointment may be required, or refer for specialist assessment.

Step 5:

Prepare the patient and the equipment to perform the **baseline FVC**.
Nose clip is not essential.

The standard^{4,5}:

- Patient is sitting comfortably
- A minimum of three acceptable FVC manoeuvres must be obtained.
- Repeatability criteria are met when there is no more than 100mls ideally (and certainly no more than 150mls in the occasional highly variable patient) between each blow. Some spirometers will inform the user when this has been achieved.
- Encourage maximum effort at the start of each blow, verbally encouraging patient to continue to exhale to achieve maximal effort
- Observe the patient as each FVC is performed to ensure they:
 - Breathe in to maximal inspiration
 - Do not obstruct the mouthpiece with their teeth or tongue.
 - There are no leaks from the mouthpiece
 - Remove false teeth if loose
- Observe the flow/volume curve as each FVC manoeuvre is being performed to identify:
 - Slow starts
 - Early stops
 - Variability in flow within manoeuvre
- Ensure the patient exhales fully and that this is demonstrated on the graph showing a time/volume plateau.
- Do not perform more than eight FVC manoeuvres in one session. If the patient is unable to achieve these standards - record why this has not been possible, arrange a further appointment to repeat the test if appropriate, or refer for specialist assessment.

Step 6:

Record baseline spirometry results in electronic or paper template, using the largest FEV₁ and VC or FVC (performed to standard) to determine the FEV₁/VC ratio.⁶

Step 7:

Post-bronchodilator testing – Post-bronchodilator spirometry testing should be performed if baseline spirometry reveals an obstructive picture, if reversibility testing is required (to differentiate asthma and COPD) and for chronic disease monitoring. Bronchodilator administration should be standardised as follows:

The standard:

- Administer bronchodilator (usually 4 x 100mcg salbutamol as single puffs via spacer or 2.5mg via nebuliser)
- Perform spirometry after 15 minutes

Step 8:

Record post-bronchodilator spirometry results in electronic or paper template using the largest post-bronchodilator FEV₁ and largest VC or FVC to determine the FEV₁/VC ratio⁶ Ensure there is also a copy of the trace attached to the patient's healthcare records. The use of spirometry electronic templates is preferred because it promotes continuity of care, effective communication across service providers, and data retrieval for audit purposes.

The standard^{4,6}:

- In primary care the VC should always be measured and recorded, as well as the FVC. The ratio (FEV₁/VC) should be calculated using whichever is the higher of the VC measurements, the baseline VC or FVC.
- Both the flow/volume and time/volume graphs must be documented within the patient's healthcare record.
- Spirometry reporting across healthcare communities should be provided in an agreed and uniform manner, ideally involving use of FEV₁, FVC and VC and using data highlighting lower limit of normal values.

Step 9:

Arrange interpretation of the spirometric results by a competent interpreter (see below).

Step 10:

Ensure the patient has a follow up appointment arranged for the results to be explained and to arrange on-going management.

3 Interpreting and Reporting of Results

Diagnostic spirometry should only be conducted by an operator trained and assessed to ARTP or equivalent standards in the performance of spirometry by recognised training bodies. Interpretation of results may be performed separately. The interpreter must be trained and assessed to ARTP or equivalent standards in the interpretation of spirometry by recognised training bodies².

Step 1:

Selecting the best value for clinical use

The best values are selected using the following standard^{6,8,9}:

- 3 technically acceptable results selected from up to 8 efforts.
- Repeatability criteria are met when there is no more than 100mls ideally (and certainly no more than 150mls in the occasional highly variable patient) between each blow
- Highest FEV₁, VC and FVC from 3 efforts meeting repeatability criteria or within 5% of each other - whichever is smaller (below 1 litre) or higher (above 1 litre)
- The highest FEV₁, VC or FVC can come from any one of the 3 efforts meeting repeatability criteria (they don't have to come from the same blow).

Step 2:

Calculating the reference value for clinical use (see example page 25)

Predicted values and normal ranges can be obtained from reference tables^{10,11}. They are calculated from the following:

- The patient's height in metres, age in years and sex is used to calculate the **mean predicted values** for FEV₁, FVC and VC.
- The actual best measurement and the mean predicted value is used to calculate the **%predicted value**.
- The **lower limit of normal (LLN)** or **range** is calculated from the mean predicted value and the residual standard deviation.
- From the mean predicted value and the residual standard deviation the **standardised residual (SR)** or Z-score is calculated.
- Z-score value below 1.64 signifies a 95% chance of the value being outside the normal reference range and is therefore abnormal.

Step 3:

Reporting the spirometry results

Adherence to criteria for preparation and performance of test (outlined above) should be reported.

The results should be reported with graphs of volume-time and flow-volume superimposing all efforts and a clear table of results showing the following values for FEV₁, FVC, and VC (PEF optional)⁵.

- The actual
- The mean predicted values
- The %predicted value
- The lower limit of normal (LLN) or range
- Abnormal values should be highlighted (e.g. bold, colour, up/down arrows)
- If results show an obstructive picture, severity should be graded as per NICE 2010¹
- The standardised residual (SR) or Z-score

Step 4:

Storing and communicating the results

Procedures for data storage should ensure:

- Secure digital back-up of the tests: results and traces should be stored electronically in such a way that the data cannot be easily lost/corrupted or altered. Many systems now offer a backup of reports (in pdf format) onto local servers and further backup onto safe storage remote from the site of measurement.
- Heat sensitive paper traces are photocopied or scanned as they can fade with time or changes in ambient temperature.
- Good quality, clearly presented reports with the minimum necessary amount of patient data to comply with information governance procedures.
- Ease of access and facility to share results between primary care and secondary care.

Step 5:

Interpretation of spirometry

The following section on interpretation and severity assessment is adapted from Levy et al⁶ with permission of the editors of the Primary Care Respiratory Journal.

Spirometric tests can show the following patterns: normal, obstructive, restrictive and mixed abnormalities.

Obstructive abnormalities

A reduction in maximum expiratory airflow relative to the maximum volume that can be expelled from the lung (the VC, measured as a forced manoeuvre) reflects an obstructive ventilatory defect due to narrowed airways. In practice, the presence of airway obstruction is suggested by a reduced FEV₁/FVC ratio, and the expiratory flow volume curve will appear concave.

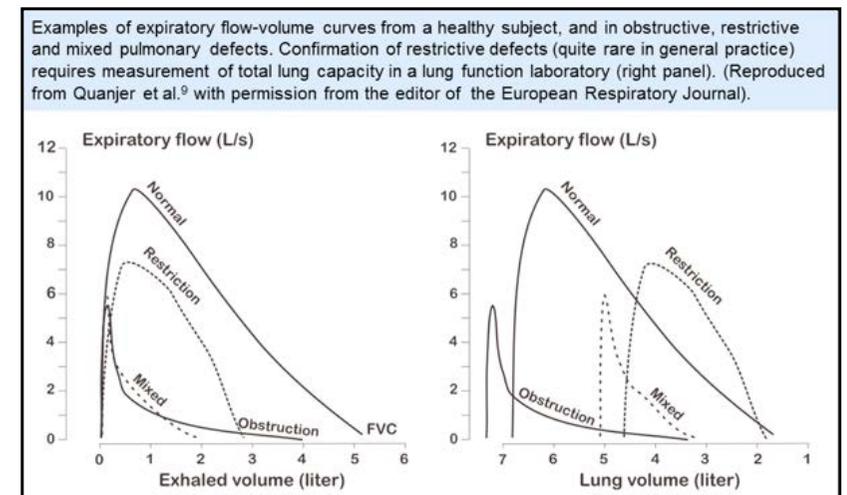
Several organisations have sought to simplify the diagnosis of airflow limitation by replacing the lower limit of normal (LLN) with a fixed cut-off of 0.70. However, since the FEV₁/FVC ratio is dependent on age, height and sex, this leads to over-diagnosis of obstructive lung disease in elderly subjects, and to under-diagnosis in young subjects. Therefore, the presence of obstructive lung disease should be based on an FEV₁/FVC ratio below the LLN.

Restrictive and mixed abnormalities

Interstitial lung disease or extrinsic disorders such as kyphoscoliosis and ankylosing spondylitis as well as obesity may cause a restrictive lung defect. This is characterised by a normal or increased FEV₁/FVC ratio and a low FVC, and the expiratory flow volume curve will appear convex.

However, the results of pulmonary function tests are highly dependent on patient co-operation. Premature termination of the FVC manoeuvre or failure to take a maximal inhalation can result in a high FEV₁/FVC ratio. Indeed the most common cause of a restrictive picture is poor technique.

A true restrictive ventilatory defect may also occur concurrently with airway obstruction if the FVC and FEV₁/FVC are both below their LLN. This represents a mixed ventilatory defect, i.e. restriction and airway obstruction. This diagnosis cannot be made on the basis of spirometry alone: if there is clinical evidence for restrictive lung disease, referral to a pulmonary function laboratory with facilities to measure Total Lung Capacity and gas transfer is recommended.



Interpretation of spirometry should never be determined solely by software from the machine or results service. The report should always include the following details⁶:

- The normality or not of the shape of the curves (Volume-Time; Flow-Volume)
- The normality or not of the measured values of FEV₁, FVC, VC and the calculated values FEV₁/FVC & FEV₁/VC
- A comment on whether the pattern fits a normal, restrictive, obstructive or mixed pattern
- If the pattern is obstructive, grading of severity as per NICE 2010¹ and GOLD 2011¹²
- The bronchodilator response is reported as showing significant reversibility or irreversibility according to current disease guidelines (asthma, COPD)
- Any comment on the quality of the measurements (e.g. only 2 efforts, poor efforts, etc.)
- A summary statement answering the original question asked by the referrer.
- Suggestions for further tests, urgent treatment(s) or referral to a specialist

Determining severity of impairment

Lung function impairment has a bearing on exercise capacity, disability and employment, quality of life, morbidity and mortality. In several studies, FEV₁, post-bronchodilator FEV₁, post-bronchodilator FEV₁ % predicted and FEV₁/height² were found to correlate best with all-cause mortality.

For general purposes severity of lung function impairment is based on FEV₁ % predicted.

Severity of Airway Obstruction FEV ₁ as a percentage of the predicted/reference value		
Degree of Severity	Stage NICE 2010 ¹ / GOLD 2011 ¹²	FEV ₁ % predicted
Mild	I	>80
Moderate	II	50-79
Severe	III	30-49
Very Severe	IV	<30

It is important to recognise that this severity grading based on degree of airflow obstruction is arbitrary, and correlates poorly with respiratory symptoms and quality of life. Additional measures of disease impact (for example dyspnoea score, exacerbation rate, validated measure of health status) are required for a comprehensive assessment of COPD severity.

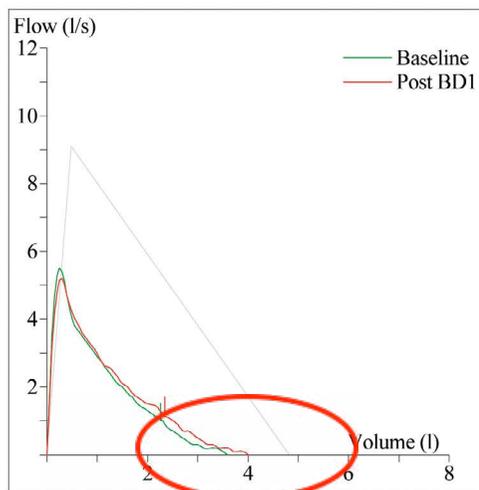
4 TOP TEN TIPS for reporting spirometry results

ID:		Alias ID:	
Name:		Exam Date:	02/04/2008 09:46
Age:	53	Origin:	Caucasian
Gender:	Male	Factor:	100
Height:	183 cm.	Weight:	170.0 kg.
Referred by:	GP	Smoker:	Ex-Smoker
		Occupation:	retired railworker

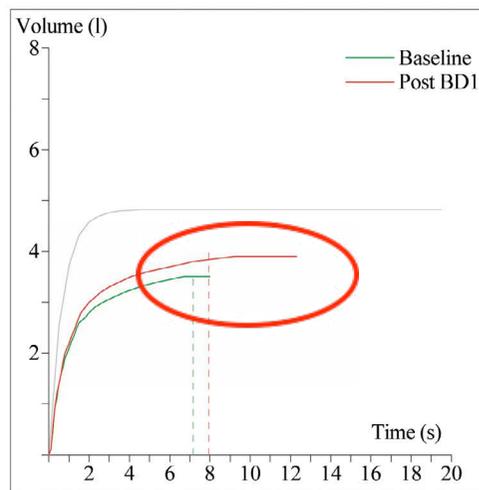
1. Patient demographics

Check patient information is entered correctly including ID, age, height gender and ethnicity Weight and BMI are also useful parameters to record. Check that the correct date and time are shown?

Best Flow Volume Loop Graph



Best Volume Time Graph



2. Technical acceptability of blows

Looking at both flow volume (FV) and volume time (VT) graphs it is important to check the technical acceptability of the blows that have been performed. In an ideal situation all blows should be super-imposed to allow a visual check for reproducibility but many machines choose the 'best blow' to utilise in the graphs. In the example opposite the graphs show that both baseline and post-bronchodilator blows were short with an early termination to the blow.

Further examples of common technical errors are illustrated on page 12.

3. Number of blows performed

In all cases a minimum of three relaxed vital capacity blows – VC, Relaxed VC (RVC) or Expiratory VC (EVC) – and three forced blows should be performed and recorded. Some machines will select the best relaxed blow and superimpose this as the VC for each blow. This does not demonstrate that three reproducible blows have been undertaken. Therefore all efforts should be recorded manually if the machine does not do so automatically. The example opposite demonstrates where the VC has been replicated for all three blows. It also shows that three baseline blows and three post bronchodilator blows have been performed.

4. Quality of the blows

Whilst the quality of the blows will have been observed by the person undertaking the spirometry it is important to check this quality is recorded. This is clearly shown in the example opposite where all good blows have been recorded. However, in this example it is important to note that this statement is not supported by the technical acceptability shown in the graphs, with the blows appearing to have been terminated early. This is a short coming of machine interpretation which should not be accepted in isolation. Other quality checks include the times that the blows were performed with an adequate time interval between baseline and post blows to enable the bronchodilator to be effective.

Medication:								
salbutamol, Tiotropium								
	VC	FEV1	FVC	PEF	VAR	Quality	Time	Date
Base	3.25	2.16	3.29	283	-7 %	Good Blow	09:46	02/04/2008
Base	3.25	2.30	3.52	271	-0 %	Good Blow	09:46	02/04/2008
Base	3.25	2.26	3.58	323		Good Blow	09:46	02/04/2008
Post 1	3.91	2.28	3.82	291	-3 %	Good Blow	10:32	02/04/2008
Post 1	3.91	2.32	3.89	331	-2 %	Good Blow	10:32	02/04/2008
Post 1	3.91	2.35	3.97	302		Good Blow	10:32	02/04/2008

Medication:									
salbutamol, Tiotropium									
	VC	FEV1	FVC	PEF	VAR	Quality	Time	Date	
Base	3.25	2.16	3.29	283	-7 %	Good Blow	09:46	02/04/2008	
Base	3.25	2.30	3.52	271	-0 %	Good Blow	09:46	02/04/2008	
Base	3.25	2.26	3.58	323		Good Blow	09:46	02/04/2008	
Post 1	3.91	2.28	3.82	291	-3 %	Good Blow	10:32	02/04/2008	
Post 1	3.91	2.32	3.89	331	-2 %	Good Blow	10:32	02/04/2008	
Post 1	3.91	2.35	3.97	302		Good Blow	10:32	02/04/2008	

5. Reproducibility/repeatability

This guidance recommends that reproducibility criteria are met when the difference between blows is no more than 100mls ideally (and certainly no more than 150mls in the occasional highly variable patient). Thus in a majority of patients there should be no more than 100mls between each FEV₁, FVC or VC measurements.

In the example opposite there is a difference of 40mls between the best two baseline FEV₁ readings of 2.30 and 2.26. The third FEV₁ is also within 100mls.

Of the three baseline FVC readings, the difference between the best two is 60mls but the third is very much an outlier with 290mls difference. This may be because the patient did not understand the technique of blowing and improved with the second and third blow. It is also worth looking at the PEF which should correlate with the best FEV₁ as both are fast manoeuvres.

The 3 post bronchodilator FEV₁s are well within the reproducible range, but the gap between the highest and lowest post bronchodilator FVCs is at the upper limit of acceptability at 150mls.

6. Measuring airflow obstruction

Airflow obstruction is defined using the ratio of the FEV₁ to the FVC or RVC – whichever is largest. A FEV₁/VC ratio below 0.7 indicates airflow obstruction. In the example above the FVC is larger than the RVC therefore the FEV₁/FVC ratio would be used. Here the ratio is $2.26 \div 3.58 = 0.63$. Because this is below 0.7, airflow obstruction is confirmed.

7. Severity of airflow obstruction (NICE 2010)

Severity is defined by using the FEV₁ % predicted and referring to the NICE 2010 guidelines (see table page 13). In the example above the FEV₁ % predicted is 61% classified as Stage 2 moderate airflow obstruction.

8. Limitations of machine interpretation

Some older spirometers still use the 2004 NICE classification (superseded by NICE 2010) to determine severity. So it is important not to rely on the machine's assessment of severity without checking the actual FEV₁ % predicted values.

9. Reversibility

The timing, dose and method of delivery of bronchodilator should be recorded to provide confirmation that tests of reversibility were performed in accordance with guidance. Reversibility is defined in the NICE 2010 guidelines¹ as significant if FEV₁ improves by more than 400mls. In the example opposite the picture is obstructive with a post bronchodilator FEV₁/FVC ratio of 59%. After bronchodilation, the FEV₁ increases by only 90 mls so would not be defined as reversible according to NICE guidelines.

Variation is based on FEV1 + FVC

Index	Base	%Pred	Post 1	%Pred	Change	[Min	Pred	Max]	Units
EVC	3.25	65	3.91	78	20	4.11	5.03	5.95	l
FEV1	2.26	59	2.35	61	4	3.00	3.84	4.68	l
FVC	3.58	74	3.97	82	11	3.82	4.82	5.82	l
PEF	323	59	302	55	-6	427	547	666	l/min
FEV1/VC	70		60		-14				%
FEV1/FVC	63	81	59	76	-6	66	78	89	%
LUNG AGE	83								Years
DYSPNOEA	4		4		0				

10. Check the clinical picture

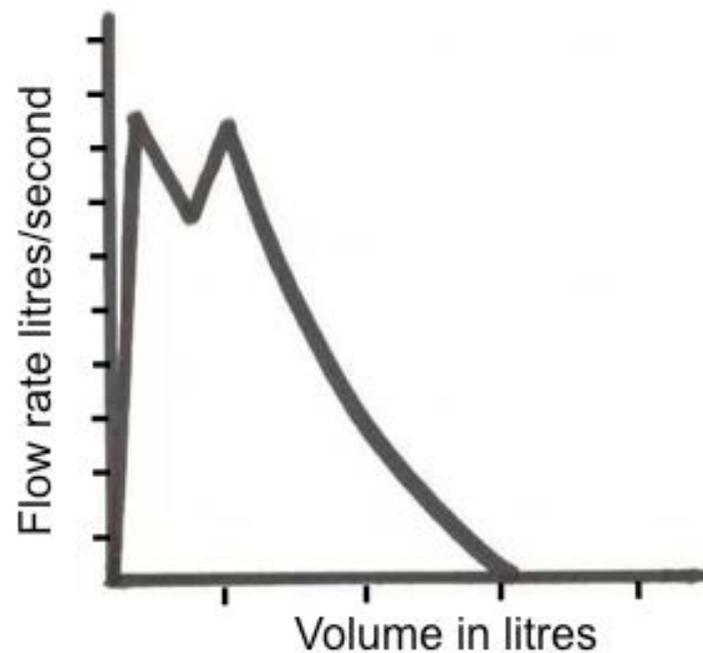
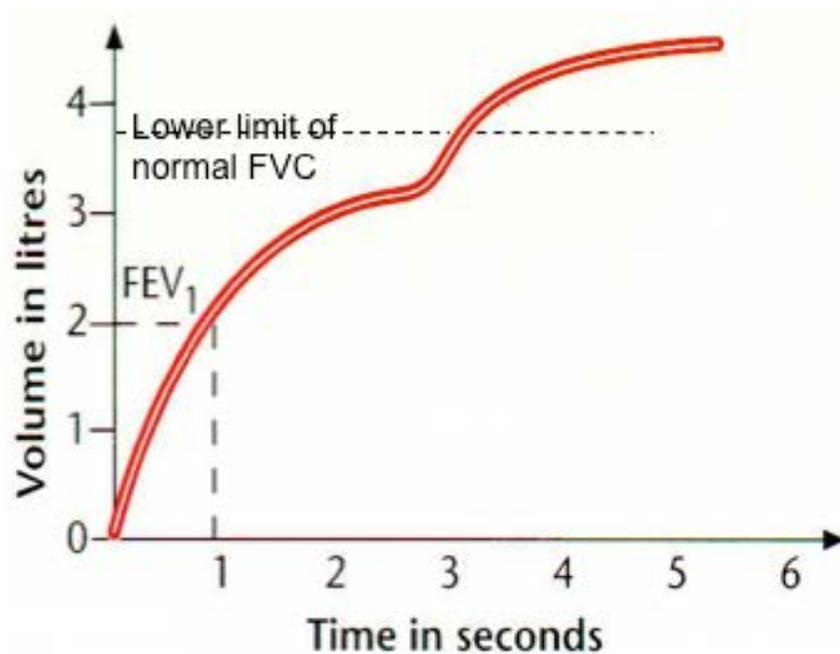
It is important not to interpret the spirometry results in isolation. Diagnosis should always be based on the history, examination and measurement of airflow. If the diagnosis is not clearly established, referral for further investigation should be considered.

5

Some Common Technical Errors in Spirometry

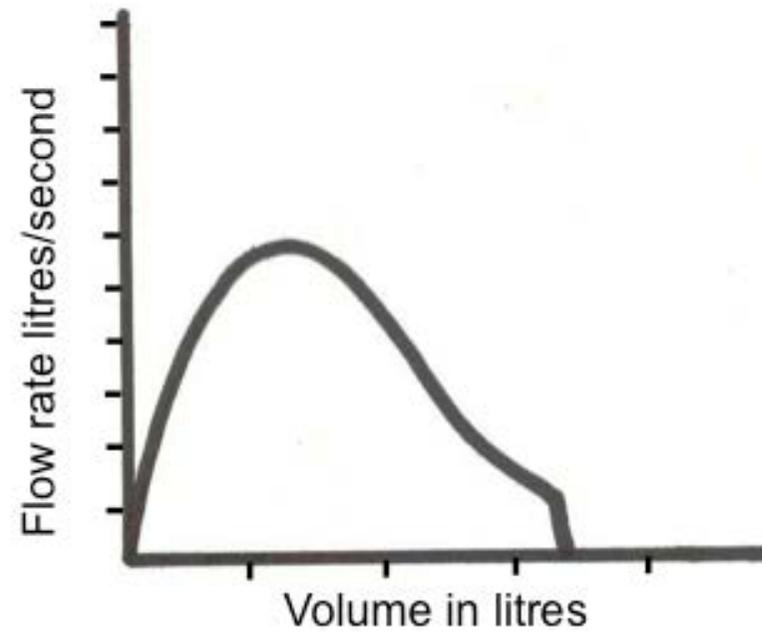
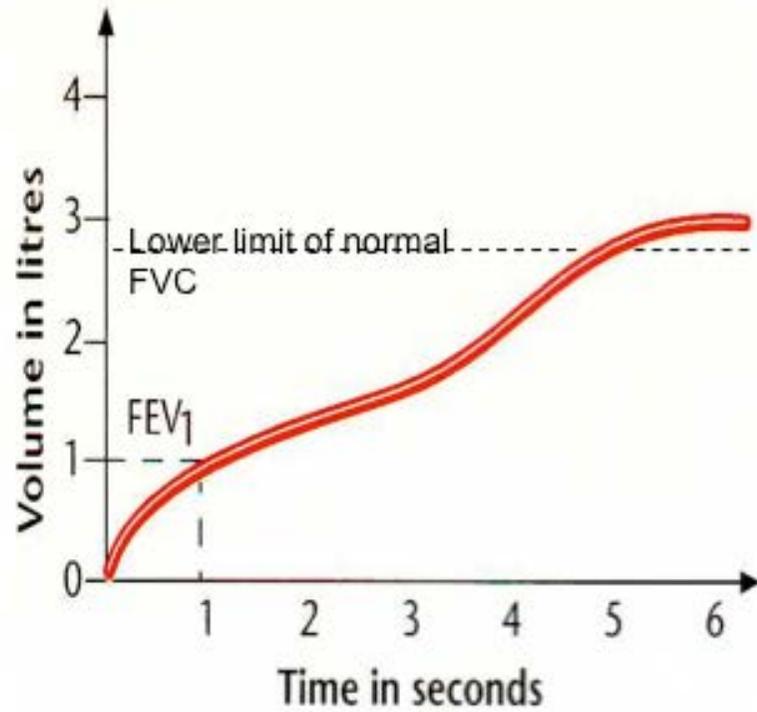
(Reprinted with permission from Education for Health)

Extra breath

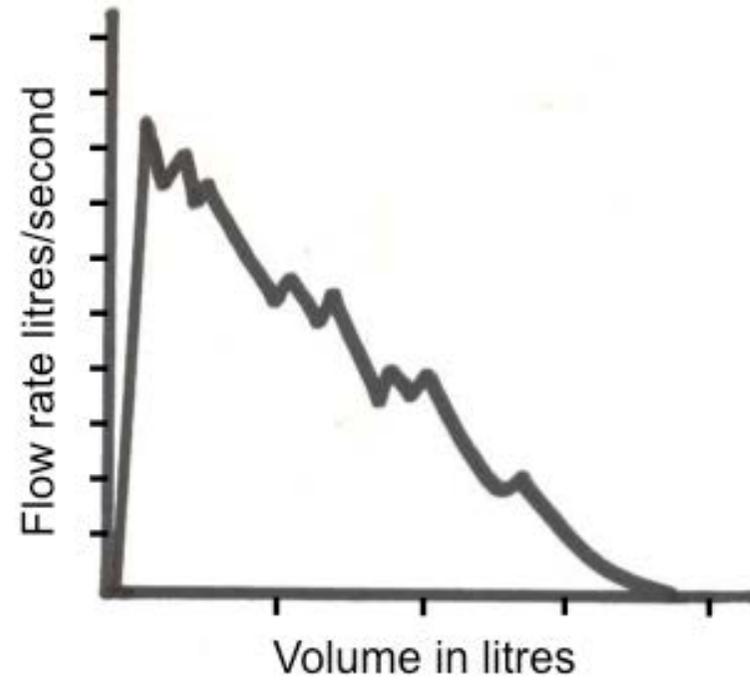
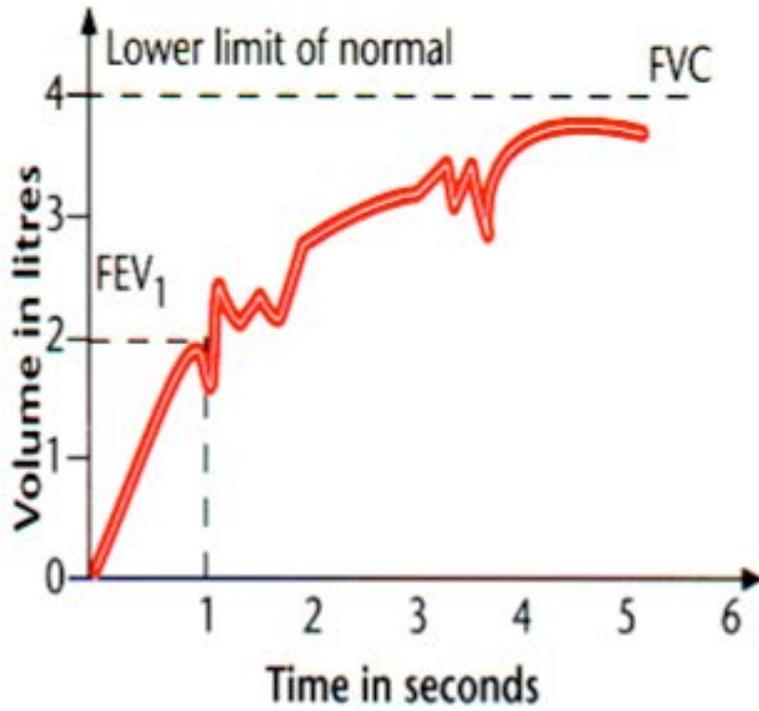


Some Common Technical Errors in Spirometry

Sub-maximal effort

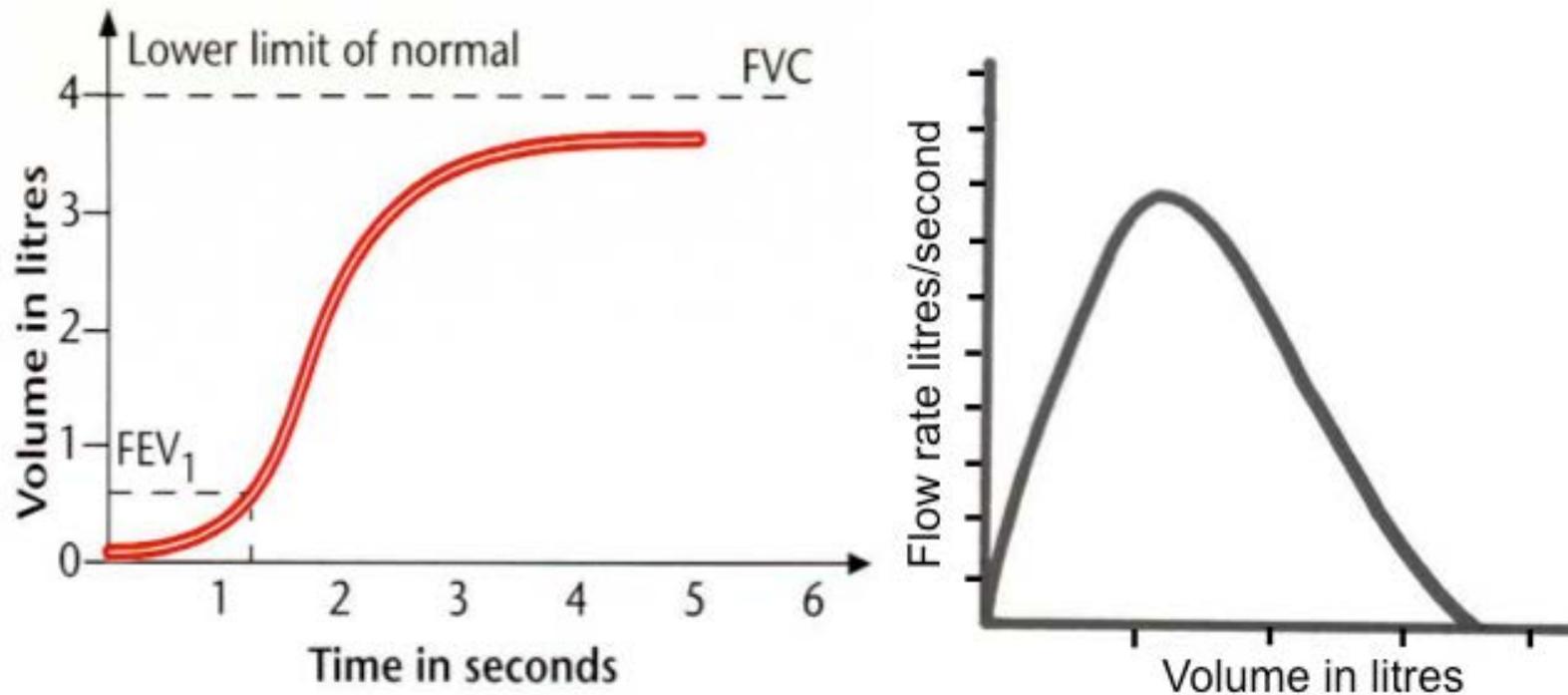


Coughing

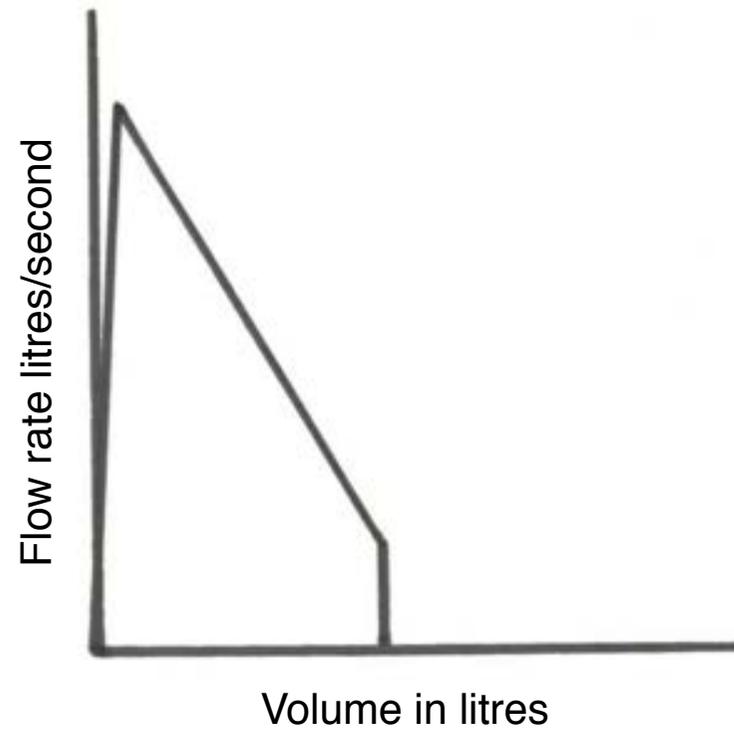
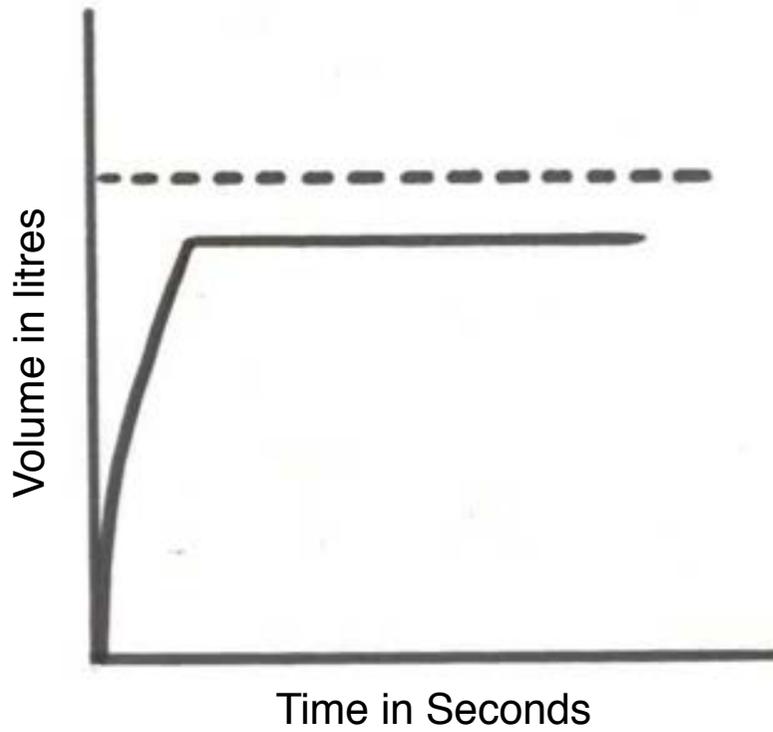


Some Common Technical Errors in Spirometry

Slow start



Early stop



Some Common Technical Errors in Spirometry

6 Quality assurance of diagnostic spirometry

To be of clinical value, diagnostic spirometry has to be performed to a high standard. If it is not, there is a significant risk that the diagnosis will be incorrect and that as a result patients will receive inappropriate and potentially harmful treatment. Providers of diagnostic spirometry therefore need to provide assurance that every spirometry test meets the necessary standards.

To demonstrate quality assurance, providers of diagnostic spirometry should:

1. Ensure that equipment and processes meet the standards in this guide.
2. Ensure that all staff performing spirometry are trained and assessed to ARTP or equivalent standards in the performance of spirometry by recognised training bodies, and that they receive regular updating².
3. Ensure that all staff responsible for interpreting spirometry are trained and assessed to ARTP or equivalent standards in the interpretation of spirometry by recognised training bodies, and that they receive regular updating².
4. Conduct quality control checks at least weekly to ensure reliability and reproducibility of results. Quality control checks should use physical controls (with calibration syringe) or biological controls using one member of staff with stable known normal values. See box page 25 for biological control method.

The results obtained are graphed and compared with those previously obtained in the same way. This will reveal any inconsistencies in the results. If there is a significant deviation from previous results, the spirometer should be recalibrated and circuitry checked. If the error remains, the equipment should be withdrawn and sent for service/repair.

5. Maintain a log of:
 - Calibration and verification records
 - Repeatability of the FEV₁, FVC, VC and PEF [in terms of absolute (e.g. 50mL) and percentage variability]
 - Biological controls
 - Feedback from external reviewer service where used

To promote quality assurance, providers of spirometry services can apply for accreditation with the Improving Quality In Physiological diagnostic Service (IQIPS) Programme (www.iqips.org.uk). IQIPS involves self-assessment and external peer assessment against a set of standards to assess performance and assist continuous improvement. The online Self-Assessment Improvement Tool (SAIT) includes specific guidance, example evidence, references and a knowledge management system to support users and share good practice.

Reference Values

A. In 2012 the Global Lung Initiative¹¹ published multi-ethnic reference values for spirometry for the 3–95 year age range.

Predicted values and normal range can be calculated from an online spreadsheet at www.lungfunction.org/tools/85-equations-and-tools/equations/151-excel-individual-calculator.html

B. Historically, predicted values and normal range have been derived from the ECSC reference values¹⁰

Example: A female patient aged 45 years, height 1.64 m performs an “actual” FEV₁ of 3.00 litres.

The Residual Standard Deviation (RSD) for FEV₁ in women is 0.38.

1. Predicted value FEV₁ (Pred) = $(3.95 \times \text{Height (m)}) - (0.025 \times \text{Age (years)}) - 2.60$
= $(3.95 \times 1.64) - (0.025 \times 45) - 2.60$
= 2.75
2. Per cent predicted FEV₁ (%Pred) = $(\text{Actual FEV}_1 / \text{FEV}_1 \text{ Pred}) \times 100$
= $(3.00 / 2.75) \times 100$
= 109%
3. Lower limit of normal/Range = $\text{FEV}_1 \text{ Pred} \pm (\text{RSD} \times 1.645)$
2.75 \pm (0.38 \times 1.645)
ULN = $2.75 + 0.63 = 3.38$
LLN = $2.75 - 0.63 = 2.12$
Range = 2.12 to 3.38
4. Standardised residual (Z-score) = $(\text{FEV}_1 \text{ Actual} - \text{FEV}_1 \text{ Pred}) / 0.38$
= $(3.00 - 2.75) / 0.38$
= $0.25 / 0.38$
= 0.66 (within normal range -1.645 to $+1.645$)

Biological Control Data

1. Select biological controls – fit and healthy adults aged 18-65 years with no respiratory symptoms, no history of lung disease and not in the third trimester of pregnancy.
2. Establish normal range and variation of FEV₁, FVC and VC for the biological control by obtaining 20 measurements over 10 sessions on different days. Record data on data sheet.
3. Obtain the mean \pm SD for each index and plot these on a graph with the mean value and \pm 1SD and \pm 2SD
4. On subsequent measurements, obtain the FEV₁, FVC and VC for the control
5. Plot out the new data to ensure that values are within \pm 1SD of the mean. If this is the case then the test on the subject can proceed.
6. If data are between \pm 1SD and \pm 2SD, then this should highlight that an error may have occurred. Recalibrate spirometer and check circuitry. Repeat data on biological control.
7. If error remains withdraw equipment from use and fully assess and revalidate

References

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