

Standardisation of spirometry

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The suggested technical specifications in this document apply to apparatus used by clinicians for the diagnosis of common respiratory diseases and are to be considered as the minimum acceptable standards. Specifications, features and practices which are desirable, but not obligatory, are also presented. It is accepted that a need exists for more sophisticated apparatus for specialised indications (e.g. for use in an academic institution for training or research, or for standardisation of other respiratory equipment). For sophisticated apparatus more stringent specifications apply, some of which can be found in the original documents.¹⁻⁴

A. Apparatus

1. Spirometers should be able to measure volumes of at least 7 litres with an accuracy of 3% or 50 ml, whichever is the greater.
2. Spirometers should be capable of volume accumulation for at least 30 seconds, time being measured with an accuracy of 1%.
3. Flow should be measured with an accuracy of 5% of 0,2 l/s between the ranges of 0 and 15 l/s. Flow meters should be linear within 25 or 50 ml/s, whichever is the greater. Baseline drift should be less than 50 ml/s.
4. The resistance of the spirometer or flow meter and tubing system should be less than 0,1 kPa/l/s at a flow of 15 l/s; the inertia of the system should be less than 0,01 kPa/l/s.
5. Graphs of the flow-volume curve should be scaled with a ratio of flow to volume at 2:1 with 5 mm/l. Should hand measurements be done on volume-time graphs, then a minimum scale of 2 cm/s is required. When a flow-volume loop or curve is plotted or displayed, exhaled flow should be plotted upwards and exhaled volume towards the right.

The rationale for including these specifications takes into account first of all the tolerance of the measuring equipment and, secondly, expectation of the normal range of values obtainable throughout the subject population. For example, the recommendation that a spirometer should be capable of measuring a vital capacity of 7 litres is based on data of 9347 coalminers of whom 95,25% had a forced vital capacity (FVC) of less than 7,5 litres (Hankinson J, Petersen M, *Am Rev Respir Dis* 1977, 115 (suppl 116)).

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Computer hardware

1. Analog-digital (A - D) converter should be a 12-bit converter.
2. The data sampling rate should be at least 100 Hz.
3. The resolution of the electronic clock should be 40 microseconds.

Computer software

1. The manufacturers of microprocessor or computer-based spirometry systems should provide some explanatory data on the algorithms used in determining derived values, especially if interpolation methods are required, and in determining the start of test and end of the FVC manoeuvre.
2. The source of reference values should be stated, together with their scientific citation, and the user should be able to select or manually enter reference values best suited to the healthy population from which subjects or patients are likely to be drawn.
3. Should the system offer a computerised interpretation, the criteria for making its diagnostic decisions should be made available to the clinician if required.
4. It is desirable to display on the screen, and on the final report, both the volume-time and flow-volume recordings of each successive attempt by the patient.
5. It is desirable to be able to select and combine expiratory and inspiratory flow-volume data from different manoeuvres.
6. A hard copy of the results must be provided by the system.
7. It should be possible to store the data on removable computer discs if the spirometer is connected to a computer.

B. Calibration

All spirometers or spirometer systems must make provision for an acceptable calibration routine which includes the facility to adjust the calibration setting(s). The latter may be different for inspiration and expiration, especially for pneumotachometers.

Volume calibration should be performed by injecting a known volume of air into the spirometer with a 3-litre calibration syringe; the spirometer must record the calibration volume to within 3% or 50 ml, whichever is the greater, under the appropriate conditions of temperature and barometric pressure (i.e. ATPS). Calibration should be performed at least 5 times across the full range of volume and flow of the spirometer at least daily, but it may be necessary to calibrate 4-hourly (in epidemiological or industrial surveys) if many tests are done in one day.

Flow is more difficult to calibrate; however, if the spirometer is a flow-based spirometer, i.e. a pneumotachometer or other flow meter is the primary measuring instrument, then the injection of a known volume would ensure calibration of volume, flow and time if the calibration volume is recorded within 3%. The injection times should

vary between 0,5 and 6,0 seconds for the 3-litre syringe so as to ensure linearity over a wide range of flows. It is important that the apparatus should be set to register volumes at room temperature so that the recorded calibration volume is expressed at ATPS, since room air is injected. If the flow meter usually heats the gas to 37°C, then the heating element should be switched off and allowed to cool to room temperature prior to calibration. The apparatus will need to be reset for measurements in a patient, i.e. 37°C.

If flow is derived from differentiation of the volume signal, then calibration of volume and time go a long way towards ensuring accurate flow measurement. An additional and desirable check on flow calibration is to integrate (measure the area under) the flow-time curve generated by injection of 3 litres; the volume thus derived should fall between 2,95 and 3,05 litres.

The measurement of **time** is less easily calibrated. This can be performed on recorders with an electronic stopwatch, and should be done at least every 3 months. (The mean of 10 measurements of 3 seconds should vary less than 5%, if less than 0,15 seconds). A biological check, such as testing a healthy subject with a known FEV₁, is an alternative option: this value should vary less than 5% from one day to the next in a healthy subject.

Correction for BTPS: Measurements of volume could be appreciably more accurate if ambient temperature and barometric pressure are taken into account.

If volume or flow recorded from test subjects is not measured at room or body temperature, as may be the case with volume spirometers and unheated flow devices positioned some distance from the mouth, the **temperature** of the inhaled and exhaled gas should be measured. It is desirable that the temperature should be measured with a thermistor or thermocouple with a rapid response and which has been calibrated against a mercury thermometer between 20° and 37°C. This is essential for the appropriate BTPS corrections to the raw data.

Comment:

1. Failure to correct volumes for the appropriate BTPS factor would lead to an 8-10% error.
2. Difficulty with a calibration may indicate the need for the apparatus to be serviced.
3. We recommend that laboratories keep a logbook in which calibration data are entered daily.

C. Subject/patient manoeuvres

Should only expiratory volumes and/or flows be measured, it is essential that a slow vital capacity (SVC) manoeuvre be performed prior to the forced expiration. If both inspiratory and expiratory FVC are measured in a single combined manoeuvre, they should be performed in that order; the inspiratory vital capacity, thus obtained, can be assumed to be equal to the expired SVC.

Comment. It is preferable to perform the forced inspiratory manoeuvre prior to the expiratory vital capacity, since this will reveal air trapping due to dynamic collapse of unstable airways (in this case, expiratory FVC will be smaller than the SVC or the inspiratory FVC).

The following procedure for the flow-volume curve is recommended when both inspiratory and expiratory flows are to be measured.

A period of quiet breathing is maintained until a constant end-tidal volume is reached for three consecutive breaths. The subject is then instructed to exhale slowly and maxi-

mally, to residual volume (RV) — the subject must be actively encouraged to 'squeeze' out the last bit of air. Once RV has been reached, the subject is exhorted to inhale as fast, forcefully and deeply as possible to total lung capacity (TLC), to hold the inspiratory effort at TLC for 1 or 2 seconds, then to exhale as rapidly, forcefully, and completely as possible for at least 6 seconds or until no more gas can be exhaled. The manoeuvre with maximal effort, from TLC to RV, is the expiratory FVC manoeuvre; and the exhaled volume from RV to TLC is the inspiratory FVC.

A noseclip should preferably be worn by the subject, particularly if the tidal volume flow-volume data is recorded. The subject should preferably perform the test in the sitting position, but the standing position is acceptable for children. The posture of the patient should be recorded on the final report, as should the use of a noseclip.

Testing for bronchodilator responsiveness

Patients on bronchodilators should discontinue medication prior to testing as follows: inhaled bronchodilator — 4 hours; theophyllin preparation — 12 hours; theophyllin (slow release) — 24 hours. Baseline spirometry measurements should include at least FVC and FEV₁.

Procedure. An adequate dose of an inhaled β_2 -adrenergic agonist should be administered. Inhalation of the aerosol must be from functional residual capacity (FRC) to TLC and inspiration should be held for 5-10 seconds before exhalation.

The tests must be repeated at least 10 minutes after administering the bronchodilator.

Criteria for a significant bronchodilator response. The following are acceptable criteria: (a) an absolute increase of > 200 ml in FEV₁ after administration of the bronchodilator; (b) an increase in FEV₁ of \geq 15% from baseline FEV₁; (c) an increase in FEV₁ of > 7% of the mean of the initial and the post-bronchodilator values may be used, particularly in children.

Comment: In view of wide intra-patient variability, PEFR measurement is not generally recommended for diagnosing reversible airflow obstruction.

D. Recommended minimum measurements

The following are the minimum primary measurements that must be recorded during forced spirometric manoeuvres: forced volume-time data: FVC and FEV₁; flow-volume curve: FVC, PEFR, PIFR, FEF₅₀ and FEV₁. The FEV₁ should be measured simultaneously with the flow-volume data.

Comment: The FEF₅₀ refers to the instantaneous expiratory flow when 50% of the FVC has been exhaled.

It is desirable that the following measurements should also be recorded during forced spirometric manoeuvres: forced volume-time data: SVC and FEF₂₅₋₇₅; flow-volume curve: FIVC and FEF₇₅.

Comment: The FEF₂₅₋₇₅ is the average expiratory flow over the middle part of the FVC; FEF₇₅ is the instantaneous flow when 75% of the FVC has been exhaled. It is preferable to perform both the SVC (or FIVC manoeuvre) and a FVC manoeuvre because a difference between the two may indicate air trapping; consequently the FEV₁/FVC may be < FEV₁/SVC (or FEV₁/FIVC) and therefore underestimate the degree of obstruction.

E. Criteria for an acceptable test

The criteria for an acceptable start and end of test are best assessed from the volume-time curve, while all other criteria for acceptability are best evaluated from the flow-volume curve.

1. Ideally, the *start of the expiratory manoeuvre* ('start of test') should be readily apparent from the volume-time recording: the initial segment of the expiratory curve should have a very steep slope. The point from which time is measured should be determined by the back-extrapolation method, illustrated in Fig. 1. It is important that the back-extrapolated volume be less than 10% of the FVC, or less than 0,1 litre, whichever is the greater; if the extrapolated volume exceeds these limits, the timed data should be disregarded. When the start of test is determined by computer, the zero time can be estimated to coincide with the time determined by back-extrapolation using the largest average volume v. time slope which occurs over any 70 ms period. The *start of inspiration* should be taken to occur when the inspiratory flow exceeds 0,5 l/s.

The *end of the forced expiratory test* should usually only occur after 6 seconds. It is considered to occur at the time at which there has been less than 0,025 litre change in volume over the previous 0,5 seconds, if the forced expiratory time is less than 10 seconds, or less than 0,04 litre change in the previous 2 seconds if the forced expiratory time exceeds 10 seconds. Criteria for the *end of forced inspiration* have not yet been published, but one method is to use the time at which the inspiratory flow falls below 0,5 l/s.

2. Peak expiratory flow (PEFR) should be produced within the first 15 - 25% of the volume expired and the ascending part of the curve to peak flow should be as steep as possible. The duration of the peak should be less than 30 ms.

Comment: If the PEFR is not easily identified or is delayed and reduced in amplitude this may indicate upper airway obstruction or, more commonly, poor initial effort.

In the former situation, the curve usually will be reproducible. If the latter is the case, the curves are generally not reproducible and instantaneous flows at lower lung volumes, and even the $FEV_{1.0}$, may be higher than on a reproducible, truly maximal expiratory flow-volume curve.

All curves in which peak flow is reached after the first 25% of the expired volume should be rejected if poor effort is the cause.

3. The downslope of the curve should be smooth and free of artefacts, such as coughing, mouthpiece or glottis closure or second inspiration. Furthermore, the RV should be reached by a gradual decrease in expiratory flow rates toward zero.

Comment: A sudden reduction of flow rates at the end of the expiration may be due to a submaximal effort and failure to exhale to RV. An erroneously smaller FVC due to an incomplete expiration will result in factitiously high FEF_{50} and FEF_{75} values. Curves in which expiratory flow suddenly decreases to zero should be accepted only if they are reproducible; in this case, the phenomenon might indicate chest wall restriction.

4. The peak inspiratory flow (PIFR) should be reached within the first 30 - 50% of the inspiratory volume and the inspiratory curve is usually convex throughout.

F. Reproducibility

Reproducibility of the tests should be assessed both graphically from superimposed flow-volume curves and from the data.

1. The goal should be to register at least two flow-volume curves that are virtually perfectly superimposable. With regard to the actual data, the FVC and $FEV_{1.0}$ should be reproducible to within 5% or 0,1 litre, whichever is the greater; the instantaneous flow rates should be reproducible to within 10%.
2. The FIVC and $FIV_{0.5}$ should also be reproducible to within 5% or 0,1 litre, whichever is the greater, and the PIFR within 10%.

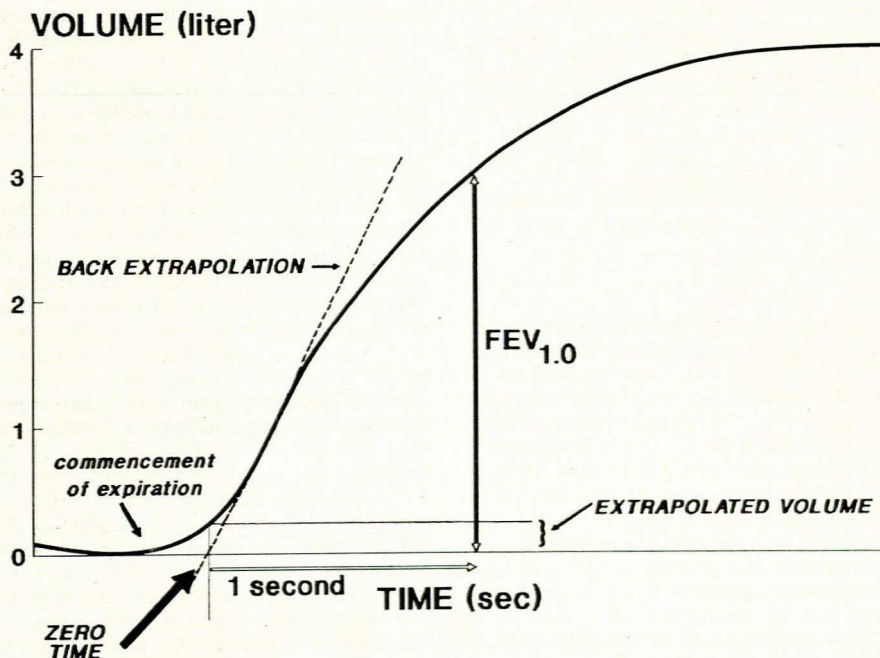


Fig. 1. Determination of 'zero-time': back-extrapolation method.

3. A minimum of three and a maximum of eight attempts should be made to achieve acceptable and reproducible curves. If acceptable, reproducible curves are not obtained, due to inability or lack of co-operation of the subject, the test must be abandoned and repeated at a later date.

Comment: It should be noted that successively smaller FEV_{1.0} and instantaneous flow values may indicate disease, e.g. extreme airway hyperreactivity or muscle fatigue.

4. The final report should display the graphs that produce evidence of the reproducibility of the test.

2. This should include the numerical data and graphic presentation of the results. It is desirable that the graphs be correctly scaled and the orientation should be as stated in section on Apparatus.
3. Evidence of the reproducibility of the final result must be provided graphically or numerically (see section on Reproducibility.)
4. Both patient and operator must see and sign the final report for tests with possible legal ramifications or which may be used in disability assessment. The patient thereby identifies the report as referring to him/her and the operator confirms that he/she assisted with the test.

G. Selection of the best test

1. Curves and data **must** meet the requirements for both acceptability and reproducibility.
2. Provided the above criteria are met, the expiratory curve with the greatest sum of FVC + FEV_{1.0} may be selected and all (flow) measurements made from this curve. Alternatively, the highest FEV_{1.0} and FVC even from different attempts, should be recorded. Similarly, the inspiratory test with the greatest sum of FIVC and FIV_{0.5} should be selected for reporting.
3. The best expiratory and best inspiratory efforts may not necessarily come from the same combined manoeuvre, and therefore the best composite curve should be constructed.

H. Final report

1. The names of the patient, attending medical doctor and operator of the spirometer must be stated together with the date and time of the test. The position of the patient while he/she performed the test should be recorded, as should the use of a noseclip.

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SELECTED REFERENCES

1. American Thoracic Society. Standardisation of spirometry — 1987: Update. *Am Rev Respir Dis* 1987; **136**: 1285-1298.
2. American Thoracic Society. Pulmonary function laboratory personnel qualifications and computer guidelines for pulmonary laboratories. *Am Rev Respir Dis* 1986; **134**: 623-629.
3. Quanjer Ph. H, ed. Standardisation of lung function testing. *Bull Eur Physiopath Respir* 1983; **19** (suppl 5): 7-27.
4. Quanjer Ph. H. Compilation of reference values for lung function measurements in children. *Bull Eur Physiopath Respir* 1989; **2** (suppl 4): 184S-261S.
5. Clausen, J.L, ed. *Pulmonary Function Testing, Guidelines and Controversies: Equipment, Methods and Normal Values*. New York: Academic Press, 1982.
6. Hankinson J.C. Pulmonary function testing in the screening of workers: guidelines for instrumentation, performance and interpretation. *J Occup Med* 1986; **28**: 1081-1092.
7. De Kock MA, Swiegers WRS, Wright R. The flow-volume curve as a mass screening test with emphasis on quality control. *S Afr Med J* 1989; **75**: 261-270.
8. De Kock MA. Longfunksies in die praktyk. *S Afr J Cont Med Educ* 1986; **4**: 31-42.
9. Hankinson J.L, Gardner R.M. Standard waveforms for spirometer testing. *Am Rev Respir Dis* 1982; **126**: 362-364.