TABLE OF CONTENTS

TABLE OF CONTENTS 10

CHAPTER 1 WHY SPIROMETRY? 14

LUNG DISEASE STATISTICS & INDICATIONS FOR USE 15
ECONOMIC COSTS: SELECTED LUNG DISEASES 18
DEFINITION OF RISK MANAGEMENT 19
ORGANIZATION OF RISK MANAGEMENT 20
SPIROMETRY AS A RISK MANAGEMENT TOOL 21

CHAPTER 2 WHAT IS SPIROMETRY? 22

BACKGROUND 23
KEY MEASUREMENTS 24
SPIROMETRY TEST DISPLAY OPTIONS 26

CHAPTER 3 CALIBRATION REQUIREMENTS 28

CALIBRATION REQUIREMENTS 29
PNEUMOTACH CALIBRATION REPORT 31

CHAPTER 4 SPIROGRAM QUALITY CONTROL 32

SPIROGRAM PATTERNS & MORPHOLOGIES 33
ACCEPTABILITY ERROR EXAMPLES 36
REPEATABILITY REQUIREMENT 39
THE NEED FOR A COMPREHENSIVE QUALITY ASSURANCE PROGRAM 41
QC REVIEW 43

CHAPTER 5 HOW TO PERFORM SPIROMETRY? 46

SPIROMETRY SIX STEP TEST PROCEDURE LIST 47
LANGUAGE (SCRIPT) TO ADMINISTER A SPIROMETRY TEST 48
PRESCREENING QUESTIONS 52
BLOOD PRESSURE CLASSIFICATION CHART 53
OSHA MEDICAL CLEARANCE QUESTIONNAIRE 54
CRITERIA TO SIT OR TO STAND AND BMI/ WEIGHT CHART 62
BODY MASS INDEX FORMULA 63
ENGLISH FORMULA 63
METRIC FORMULA 63
FAINTING DURING SPIROMETRY 64
WHY THREE TRIALS 65

COMMUNICATION TIPS 66
DISTRIBUTION OF BEST AND SECOND BEST TRIALS 67
CIRCADIAN VARIATION 68
PULMONARY FUNCTION REPORT 69

CHAPTER 6 LUNG ANATOMY 70

LUNG VOLUME NOMENCLATURE 71
LUNG ANATOMY AND PHYSIOLOGY 72
DIAGRAM OF THE LUNGS 74
LUNG DEFENSE MECHANISMS: SUMMARY 75

CHAPTER 7 LUNG PATTERNS 76

CATEGORIES OF LUNG DISEASE 77
CATEGORIES: CAUSE AND EFFECT 78
OCCUPATIONAL LUNG DISEASES 79
ASBESTOS RELATED DISEASES 82
EMPHYSEMA 83
ASBESTOSIS 84
COMMON QUESTIONS ABOUT OBSTRUCTION 85
COMMON QUESTIONS ABOUT RESTRICTION 86

CHAPTER 8 MANUAL CALCULATION OF TEST RESULTS 88

CALCULATION OUTLINE 89
MANUAL CALCULATION EXERCISE 90
DETERMINING THE ATPS VALUES FOR FEV_1 91
DETERMINING THE ATPS VALUES FOR FVC 91
CALCULATING THE FEV1% 91
USING THE BTPS CF TABLE 92
CALCULATE THE BTPS CORRECTED VOLUMES 92

CHAPTER 9 SPIROGRAM INTERPRETATIONS-PATTERN RECOGNITION 94

INTERPRETING RESULTS USING *PERCENTILES* TO DETERMINE THE LOWER LIMIT OF NORMAL 95
COMPARING OBSERVED TO PREDICTED NORMAL VALUES 96
GUIDELINES FOR ASSESSING IMPAIRMENT 100
TREND ANALYSIS AS USED IN SURVEILLANCE 101
COMPARISON SPIROMETRY (TREND ANALYSIS) REQUIRES OPTIMAL QUALITY CONTROL 102
SPIROMETRY IN RESPIRATORY SURVEILLANCE PROGRAMS 103
DATA MANAGEMENT SOFTWARE PROGRAMS 104
EXPECTED ANNUAL DECLINE IN PULMONARY FUNCTION VALUES 104
SPIROGRAM INTERPRETATION-PATTERN RECOGNITION 105

CHAPTER 10 WHEN AND WHERE TO PERFORM SPIROMETRY 108

ATS RECOMMENDATIONS 109
SPIROMETRY FOR RESPIRATOR WEARERS 110
CIGARETTE SMOKERS 112
TESTING ENVIRONMENTAL CONTROLS 113
RECORDKEEPING 114
CLEANING AND STERILIZATION AND PROPER USE OF SENSORS & FILTERS 115

CHAPTER 11 SPIROMETER TYPES & SPECIFICATIONS 116

A REVIEW OF VOLUME DISPLACEMENT AND FLOW MEASUREMENT SPIROMETERS 117
VOLUME DISPLACEMENT SPIROMETERS 119
REVIEW OF FLOW MEASUREMENT SPIROMETERS 122
ATS/ERS MINIMAL SPIROMETER PERFORMANCE STANDARDS 126
GRAPH SIZES 127
DIAGNOSTIC SIZE GRAPHS 128
VALIDATION SIZE GRAPHS 129
EXAMPLES OF SPIROMETER TYPES BY MANUFACTURER 130

APPENDIX 132

ATS/ERS SPIROMETRY 2005 STANDARD APPENDIX 1
ATS/ERS SPIROMETRY STANDARD, 2019 APPENDIX 2
ACOEM POSITION STATEMENT ON SPIROMETRY APPENDIX 3
OSHA – SPIROMETRY TESTING IN OCCUPATIONAL HEALTH PROGRAMS APPENDIX 4
REVIEW OF OCCUPATIONAL HAZARDS APPENDIX 5
SPIROMETRY FOR CHILDREN APPENDIX 6
LATEST PUBLICATIONS APPENDIX 7

Chapter 1

WHY SPIROMETRY?

LUNG DISEASE STATISTICS & INDICATIONS FOR USE

This manual brings together the views of the American Thoracic Society (ATS) and the European Respiratory Society (ERS) in an attempt to harmonize Spirometry testing standards that can be applied more widely in the United States and the European Union. Details of the ATS/ERS 2019 Standardization of Spirometry are given in Appendix 1.

Spirometry is fundamental in the assessment of general respiratory health. Spirometry enables measuring the effect of a disease on lung function, assessing airway responsiveness, monitoring disease course or the result of therapeutic interventions, assessing preoperative risk, and determining a prognosis for many pulmonary conditions. Spirometry is a valuable tool that provides important information to clinicians which is used together with other physical findings, symptoms, and history to reach a diagnosis.

Indications for Spirometry

Diagnosis:

- To evaluate symptoms, signs, or abnormal laboratory test results
- To measure the physiologic effect of disease or disorder
- To screen individuals at risk of having pulmonary disease
- To assess preoperative risk
- To assess prognosis

Monitoring:

- To assess response to therapeutic intervention
- To monitor disease progression
- To monitor patients for exacerbations of disease and recovery from exacerbations
- To monitor people for adverse effects of exposure to injurious agents
- To watch for adverse reactions to drugs with known pulmonary toxicity

Disability/impairment evaluations:

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

Other:

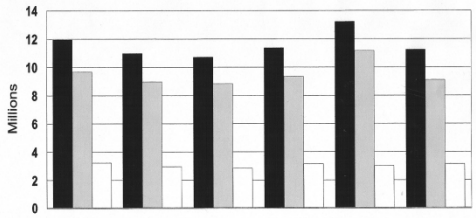
- Research and clinical trials Epidemiological surveys
- Derivation of reference equations
- Preemployment and lung health monitoring for at-risk occupations
- To assess health status before beginning at-risk physical activities

Respiratory diseases in America are reaching epidemic proportions; an estimated 35 million individuals of all walks of life are affected. Chronic Obstructive Pulmonary Disease (COPD) is the fourth leading cause of death in both the United States and Europe. Tobacco smoke is by far the most important risk factor for COPD followed by genetic predisposition. The insidious characteristics of lung disease demand routine testing to ensure detection early enough to initiate effective therapy or changes in lifestyle.

It is a fact...

- Lung related diseases are the single largest cause of physical handicaps in the nation today
- Nearly 35 million Americans are affected
  Annual cost of lung disease in the U.S. is approaching 61 billion dollars annually
- COPD is the fastest rising cause of death (4th leading cause), rising faster in women than in men.
- COPD alone accounts for approximately 20 million physician office visits annually to physicians in private practice
- Over 15 million Americans are now exposed to dusts, fumes and chemicals which can cause occupational lung diseases.
- Work related lung disease deaths exceed 100,000 annually worldwide.

NUMBER OF COPD CONDITIONS IN ADULTS, AGED 18 YEAERS AND OLDER, 1997-2002



	1997	1998	1999	2000	2001	2002
■ COPD	11,944,469	11,016,953	10,710,142	11,388,478	13,266,334	11,226,294
⊡ Chronic Bronchitis	9,667,981	8,977,160	8,847,646	9,354,982	11,198,602	9,113,581
□ Emphysema	3,217,737	2,959,516	2,798,963	3,124,699	2,983,598	3,131,410

Source: National Center for Health Statistics. National Health Interview Survey, 1997-2002

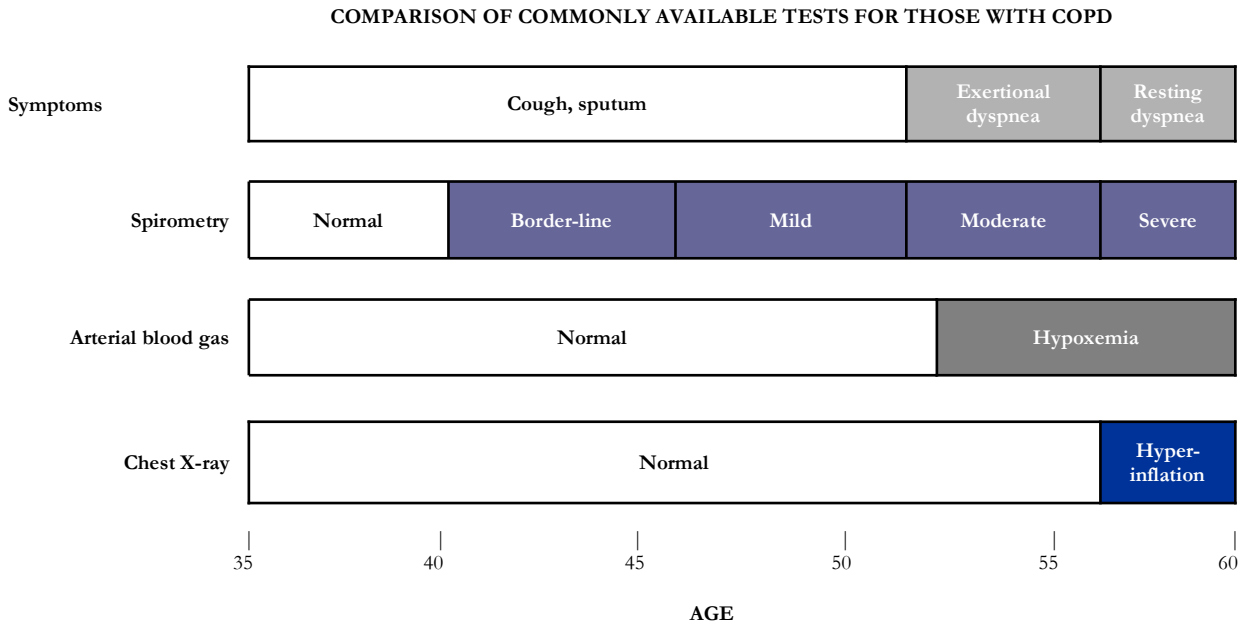
Notes:
(1) COPD totals do not take into account the overlap of persons with both diseases. Therefore, COPD totals will be lower than the sur of chronic bronchitis and emphysema estimates.
(2) Chronic bronchitis estimates indicates point prevalence and emphysema estimates represents period prevalence.

Spirometry is the only test available to primary care physicians for the early detection of COPD. ***"Early" is defined as "before significant symptoms occur". There is general agreement that the course of COPD is usually slowly progressive, usually extending over a period of more than twenty years and if not detected early, would go on to cause substantial morbidity and mortality.***

Although cough, sputum production, and minor wheezing may occur early in the course of COPD, they are non-specific symptoms that are usually of no concern to the subject. The most important symptom from the subject's point of view is dyspnea upon exertion. Unfortunately, this symptom may be disregarded by the subject merely as evidence of "being out of shape" or overweight. Most subjects wait until they have dyspnea with only minor exertion before they consult a physician for this symptom, but their disease is already moderately advanced.

Airflow update mayo pulmonary services vol. 2, n 2 1984

Note from the diagram that during the years prior to the onset of dyspnea, only spirometry is likely to be abnormal. Only spirometry can detect COPD 5 to 10 years before the onset of significant symptoms.

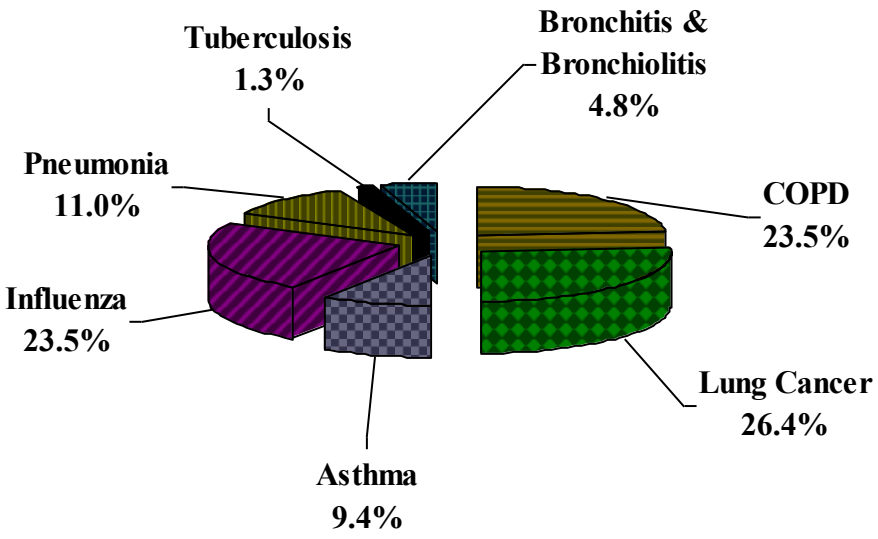


AIRFLOW UPDATES Vol. 2 No. 2 1984 Mayo Pulmonary Services

Lung function normally declines slowly after about **25** years of age. The spirometric index of lung function which is most useful is the FEV_1, which declines linearly with age in the general population, at the rate of approximately **30 ml/yr**. There is an acceleration of the normal decline of the FEV_1 when a patient has COPD.

ECONOMIC COSTS: SELECTED LUNG DISEASES

ECONOMIC COSTS of selected Lung Diseases in the USA



Total Economic Costs: $106+ Billion

Total Economic Costs are Comprised of:
Direct expenditures $81 Billion (costs incurred for the treatment and care of patients),

- **Indirect costs** $25 Billion (the value of losses in output due to morbidity or premature mortality).

U.S. Department of Health & Human Services

DEFINITION OF RISK MANAGEMENT

Spirometry falls within the definition of risk management in a company medical surveillance program, which is defined as: The Identification, Evaluation & Control of Threats to a Business Enterprise, and is made up of the following components.

1 **Restrictive Legislation**
2 **Government Interference and Fines**
3 **Loss of Skilled Personnel Due to Morbidity or Mortality**
4 **Increased Risk of Litigation**
5 **Increased Worker Compensation & Health Insurance Costs**
6 **Competition**
7 **New Technology**
8 **Fire and Theft**

Items 1-5 relate to worker health and fall under the area of Risk Control- Risk Reduction. (see organizational chart on page (20).

The organizational chart on page 20 shows the relationship between each component as part of a Risk Management Program.

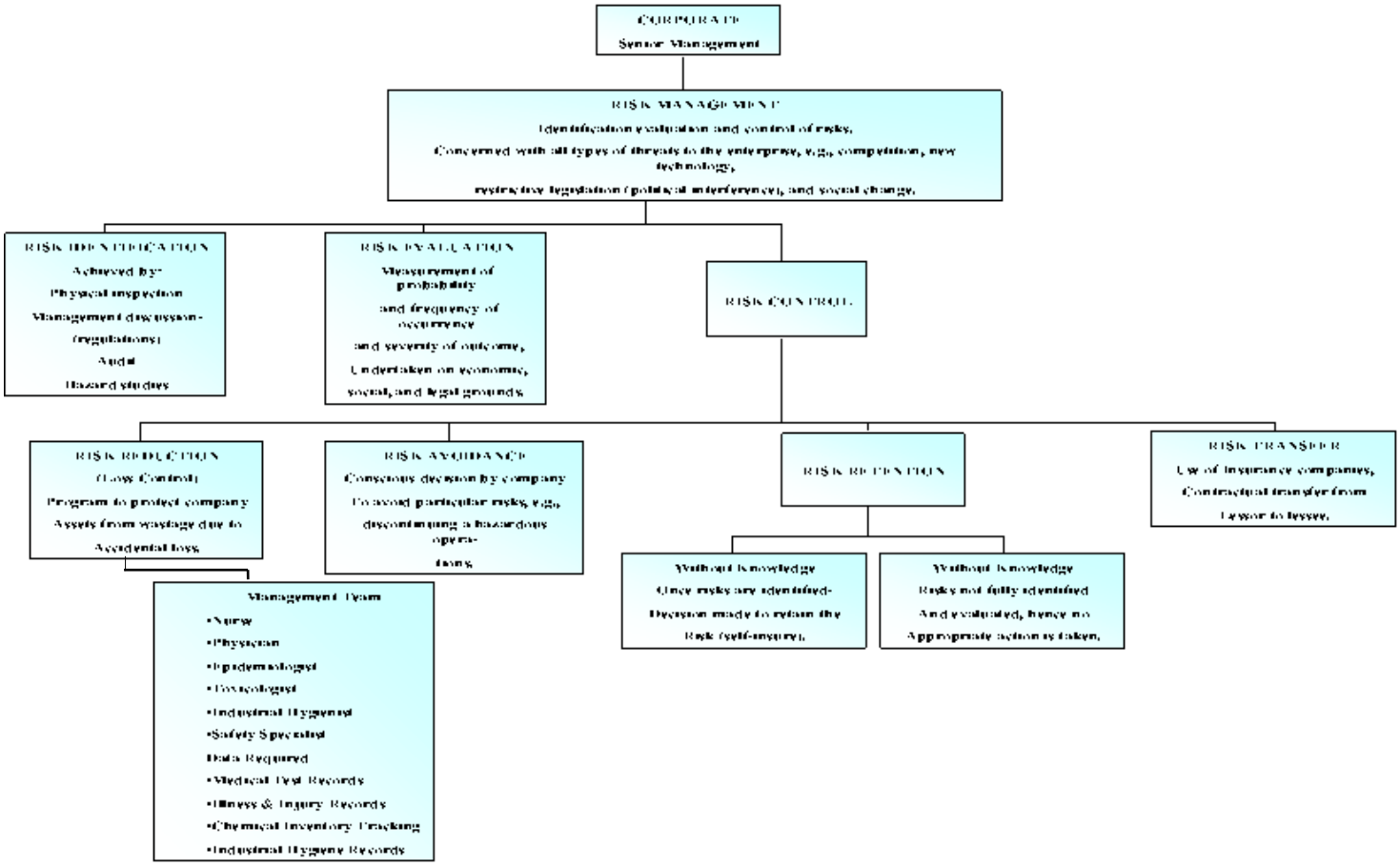
Worker health protection falls under *Risk Control* and is usually expressed in terms of Primary, Secondary, and Tertiary prevention.

Primary Prevention is an intervention before biologic onset of disease. An example would be the workplace characterization of industrial exposures that might be precursors of disease. This evaluation would be conducted by trained Industrial Hygienists using handheld or area dosimeters. Further prevention of occupational lung disease is accomplished by use of fitted personal protective respiratory devices (respirators) to reduce the level of contaminants to which workers are exposed.

Secondary Prevention is an intervention when disease can be detected at a stage before it is symptomatic. This is accomplished by the use of the ATS/ERS/OSHA approved spirometry equipment and testing procedures as part of a regular surveillance examination by **trained** spirometry technicians. Such surveillance data is then used for individual or group trend analysis to detect dynamic changes before they become abnormal.

Tertiary Prevention, or Control, is used to define and implement quantitative intervention after the onset of identifiable symptoms through entry into a healthcare system in order to delay, arrest, or reverse the course of COPD. An example is the discouragement of smoking for individuals, a measure that may arrest or reverse the conditions.

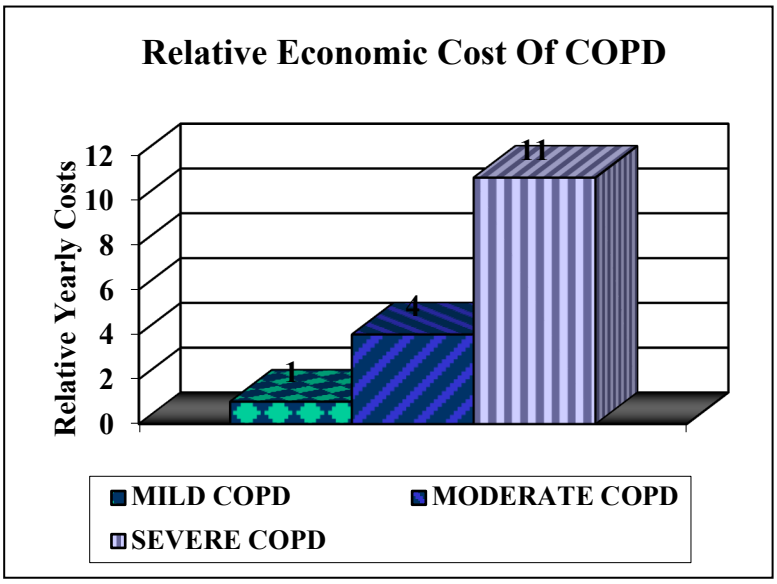
ORGANIZATION OF RISK MANAGEMENT



SPIROMETRY AS A RISK MANAGEMENT TOOL

NIOSH ranks Lung Diseases as one of the most common causes of occupational disease and disability. A technically superior program of respiratory surveillance allows company generated data to meet all medical, legal and regulatory agency audits, as well as provide a mechanism for reducing company health care benefit costs, plus costs associated with loss of worker productivity.

An effective respiratory screening and surveillance program can result in significant health cost savings to a business. It has been shown that the yearly costs to identify and treat workers with moderately advanced COPD is fourfold greater than if the condition had been detected in its mild state, and eleven-fold greater when identified in its severely advanced state. Given the average 14 - year life span remaining to those diagnosed with severe COPD, the accumulated health care costs alone are impressive.



Tuchman, M.S. Screening for Adult Respiratory Disease ATS News Summer 198

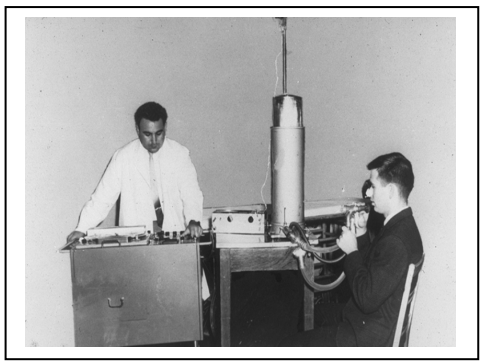
Chapter 2

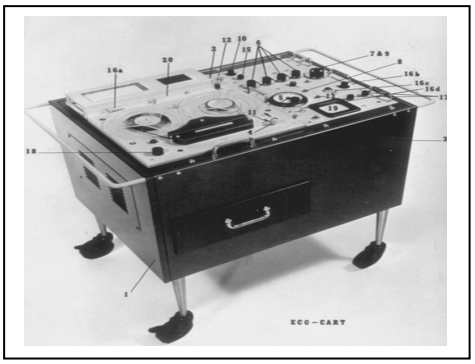
WHAT IS SPIROMETRY?

BACKGROUND

Spirometry (Spiro=breath, Metry=measurement) is a basic test of pulmonary function, and was first developed by the English physician, Dr. John Hutchinson in 1846. Spirometry is the most frequently used test of pulmonary function, although other more complicated tests may be performed when spirometry results are abnormal. These tests include Residual Volume and Total Lung Capacity measurement, Helium dilution, Nitrogen washout, Body Plethysmography, Exercise testing, Diffusing capacity and Blood Gas Analysis.

Until the early 1960's, all spirogram measurements were calculated using hand measurement techniques, which was both time consuming and tedious. The Medical Systems Development Laboratory of the United States Public Health Services (USPHS) developed the first computerized spirometry system to automatically measure the spirogram. This was accomplished by modifying a water seal spirometer to give an electronic output of its volume measurements and capturing that information on a custom-made data acquisition unit using a standard reel to reel tape recorder (refer to the pictures below). This tape was encoded with subject demographic information and then converted to a digital tape ready for computer analysis.





Spirometry has multiple purposes:

Spirometry can serve as a screening test of general respiratory health in the same way that blood pressure provides important information about general cardiovascular health. This application of spirometry may apply to a pre-employment offer.

Spirometry is used to evaluate asthma patients and their treatment.

Spirometry is also used to provide trending of lung function loss over time. If someone's downward trend line is greater than expected, it may be a sign of a detrimental exposure from either smoking, or an airborne contaminant possibly associated with work.

However, on its own, spirometry does not lead clinicians directly to a diagnosis. To diagnose, we need other signs and symptoms and medical history.

KEY MEASUREMENTS

Spirometry measures two basic lung characteristics; **lung volumes and airflow rates**. Lung volumes are determined in spirometry by measuring:

Vital Capacity: (VC) that volume of air exhaled after a maximal inhalation. This maneuver can be done slowly **(SVC)** or forced **(FVC)**. Vital Capacity is a significant measurement since many diseases result in reduced volume levels. **FVC** is measured in liters **(L)** and is usually reduced when Restrictive Lung Disease is present.

FIVC: Forced Inspiratory Vital Capacity measures the maximal inspiration following a maximal expiration.

FEV_1: (L) The volume of air in liters expired at a maximal rate in the first second **(FEV_1)** is one of the more frequently used parameters for determining definitive obstruction.

%FEV: When compared as a percentage of Forced Vital Capacity **(FEV_1/FVC x 100)**, also known as the **% FEV_1**, or ratio, serves as an indicator for grading the seriousness of obstruction and is particularly useful in identifying Small Airway Obstruction.

FEV_6: (L): When the subject does not exhale completely, the volume accumulated over a shorter period of time (e.g. 6 s) may be used as an approximate surrogate for FVC. When such surrogates are used, the volume label should reflect the shorter exhalation time (e.g. FEV_6). FEV_6 has been increasingly considered a reasonably reliable surrogate for FVC and can be used for normalizing FEV_1 (e.g. FEV_1/FEV_6). Recording FEV_6 seems to have the advantage of being more reproducible than FVC, being less physically demanding for patients and providing a more explicit EOT.

$FEF_{25-75\%}$: (formerly called MMEF) gives additional information about flow rates occurring later in the expiration. This test measures the average flow occurring during the middle half of the Forced Vital Capacity maneuver. The $FEF_{25-75\%}$, is measured in liters per second (L/sec) and is considered by some as a more sensitive indicator of Small Airway Obstruction and hence a more sensitive detector of early stages of disease since obstruction generally begins in the small airways and works its way up into the larger airways as the disease progresses. It should be noted however, that this measurement is highly dependent on the validity of the FVC and the level of expiratory effort so should only be used with great caution.

The **Peak Expiratory Flow: (L/sec)** (PEF or PEFR) is the highest flow rate attained during the maneuver. But being so effort dependent, it has little quantitative value except for tracking trends from peak flow meters in asthma patients. However, it is an excellent indicator of initial thrust or effort, so has significant quality control value, when displaying data as a Flow-Volume Curve. Instantaneous and peak flow rates are measured in liters per second (L/sec).

In summary, the FVC spirometry test can be described as evaluating the Bellows function of the lung, since air movement can be impaired in the presence of developing lung disease.

The following table identifies each measurement usually made from the Spirogram in addition to its proper definition and relative significance.

SPIROGRAM MEASUREMENTS

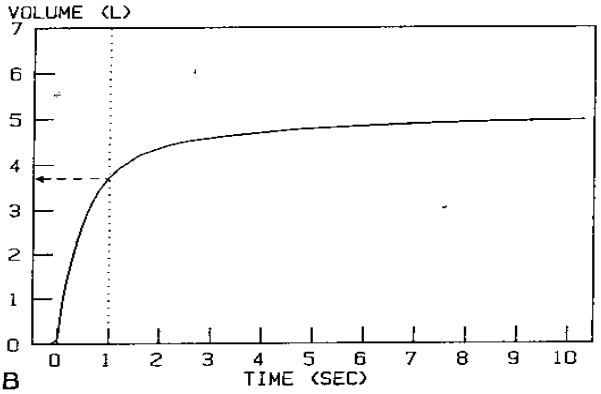
Abbreviation	Tests/Units	Definition	Measurement Significance
1. FVC (L)	Forced Vital Capacity liters (L) (BTPS)	The maximal volume of air exhaled with maximally forced effort from a maximal inspiration.	*FVC is Decreased* in **restrictive** disorders and severe obstructive impairment.
2. FEV_1 (L)	Forced Expiratory Volume1 second (L)	Maximal volume of air exhaled in the first second of the FVC maneuver, from a position of full inspiration.	*FEV_1 is Decreased* in **obstruction** of mid to large airways. Used to GRADE SEVERITY of an obstructive impairment.
3. FIVC	Forced Inspiratory Vital Capacity	Maximal Inspiration Followed by a Maximal Expiration	FIFV provides a measure of forced inspiratory VC. It is a maximal effort to return to TLC to complete the Flow Volume Loop (FVL).
4.FEV_6 (L)	Forced Expiratory Volume 6 seconds (L)	Volume of air forcefully exhaled over six seconds.	Used as a surrogate for the FVC
5. FEV_1/FVC % Expressed as %FEV_1 (referred to as the Ratio) Some software will abbreviate as %FEV_1	Forced Expiratory Volume Ratio %	A ratio of FEV_1 to the Forced Vital Capacity expressed as a percentage.	**Ratio** is *Decreased* in **small airway obstruction**. Used to DETECT first signs of obstruction. *Increased* with restrictive impairment.
6. $FEF_{25-75\%}$(L/sec)	Forced Expiratory Flow in liters/ second	The mean expiratory flow rate over the middle half of the forced vital capacity.	Used with FEV_1/FVC% (ratio) to confirm small airway obstruction.
7. PEFR (L/sec)	Peak Expiratory Flow Rate (Peak Flow) liters/ second	The maximum flow rate attained during a forced expiratory maneuver.	Of *limited value* because it is very dependent on patient effort. *Decreases* in large and upper airway obstruction.

SPIROMETRY TEST DISPLAY OPTIONS

There are various types of spirometers available for conducting this test. All of the key types are discussed in chapter 4. Each is capable of producing graphs similar to those below. For the past 100 years *Volume-Time* (V/T) spirograms have displayed expired volume as a function of time. Since the mid-1970's *flow-volume* (F/V) spirograms have also become common, showing expiratory flow rate as a function of expired volume. Both displays are critical in assessing the technical quality of a test and determining whether a patient is normal/healthy, obstructed or restricted.

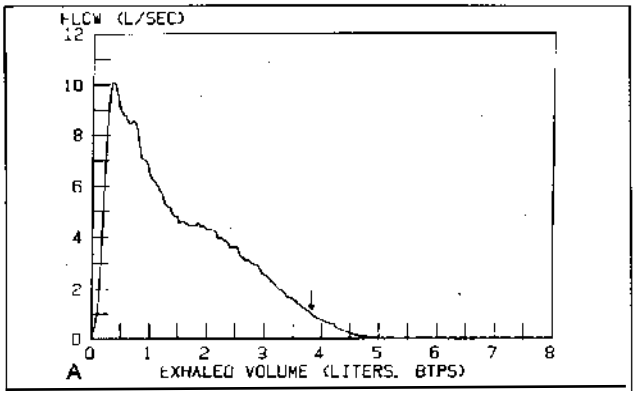
1. VOLUME-TIME

Volume (L) exhaled in liters plotted against time elapsed in seconds. This display allows for the closer inspection of the latter part of the curve, to determine if a one second plateau was achieved. A one second plateau establishes **EOFE** (**end of forced expiration**). The Volume-Time display also allows manual measurement of the FEV_1, the FVC, and total exhalation time (seconds).

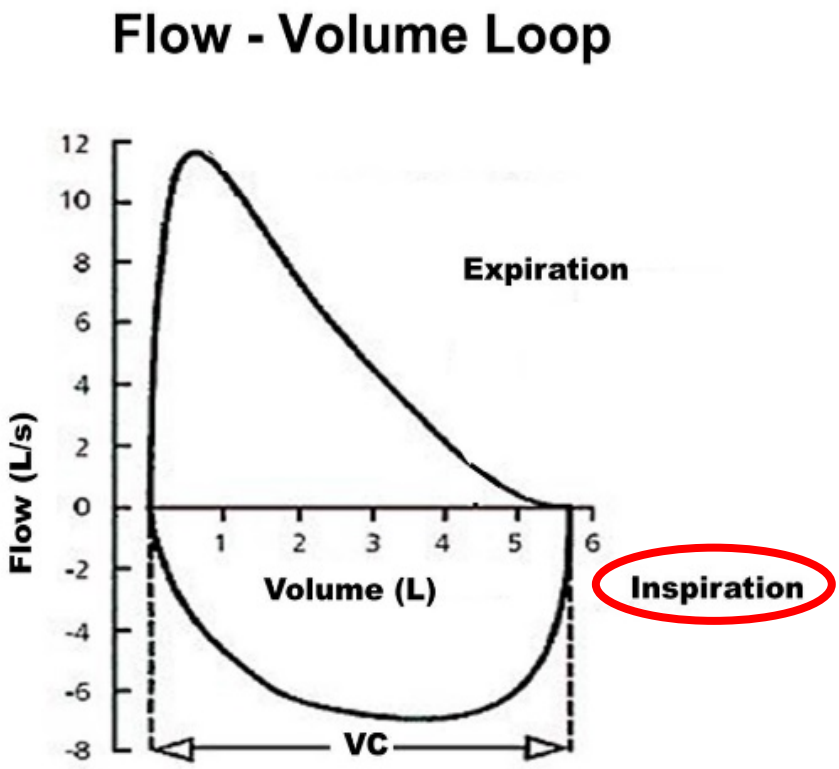


2. FLOW-VOLUME – Expiratory Only

Flow Rate in liters per second (L/sec) plotted against Volume exhaled in liters (L). This display permits a closer inspection of the beginning part of the curve to determine whether or not the test was "acceptable". "Acceptable" tests are good tests that were performed properly with maximal effort. We also use this Flow-Volume display to detect abnormalities at a glance. The shape will reflect both obstructive and/or restrictive abnormalities.



3. **FLOW-VOLUME LOOP (FVL) – Expiratory - Inspiratory**
   The same is true for the FVL as the FVC when looking at the Expiration portion of the graph but when the EOVC is reached, you have the subject take in a "deep" inspiration. The "loop" can show upper airway disease.



Chapter 3

CALIBRATION REQUIREMENTS

CALIBRATION REQUIREMENTS

PERFORM CALIBRATION, LEAK AND LINEARITY CHECKS.

1. Calibration Syringe Specifications

The ATS/ERS standard stresses the importance of documenting a daily check of the volume calibration of your spirometer using a 3- liter syringe. (ATS/ERS Standardization of Spirometry – 2005 Eur Respir J 2005:26-338) Syringes must meet the accuracy requirement outlined in the Standard, which is: 15 mls or 0.5% (for the 3 L syringe). **To check the syringe for leaks each month**, attempt to empty the syringe with the outlet occluded (use hard rubber stopper or palm of hand). If the syringe exhibits a leak, do not use for calibration. Replace the syringe. **Always perform a "leak check" after transporting the syringe**. If a syringe is dropped, it should be considered out of calibration until it is rechecked.

2. Volume Spirometers: Calibration Procedure

a. Daily Leak Check.
b. Daily Calibration check, insert 3L at medium speeds (±3.0% accuracy). and more frequently during high volume testing.
c. Quarterly Chart speed Check (at least 20mm/sec ± 2% accuracy).
d. Quarterly Range check over entire volume range.

3. Flow Spirometers: Calibration Procedure

a. Daily Visual leak check, when hose is used.
b. Daily Calibration check, by inserting 3L at FAST (1 second), MEDIUM (3 seconds) and SLOW (6 seconds) speeds. Each must meet the ±3.0% accuracy requirement.
c. To check the flow spirometer for linearity, repeat the 3-speed calibration routine described in paragraph b, three times successively. This is to be done weekly. All must meet the ± 3.0% criteria. This is called a **Weekly Linearity Check.**

4. Calibration Calculations

The ± 3.0% used to determine volume accuracy is a combination of the Spirometric volume accuracy of ± 2.5% and the syringe accuracy +-0.5%

a. **The equation to determine the percent of error is:**

$$\frac{\text{Measured Volume - Syringe Volume}}{\text{Syringe Volume}} \times 100 = \%$$

calibration is valid if it is within ± 2.5% of 3.00L for each speed.

b. **Quick Check on Spirometry accuracy:**

3.0% of the syringe value of 3.00 L equals .09 L. By adding .09 L to the 3.00 L you obtain the upper limit of acceptability: 3.09 L. By subtracting the .09 L from 3.00 L you obtain the lower level of acceptability: 2.91 L. The range of acceptability is:

2.91 L----------3.09 L

By measuring the 3L Calibration Volume signal on the graph paper, if the measured value falls between 2.91 L to 3.09 L, the spirometer is in calibration.

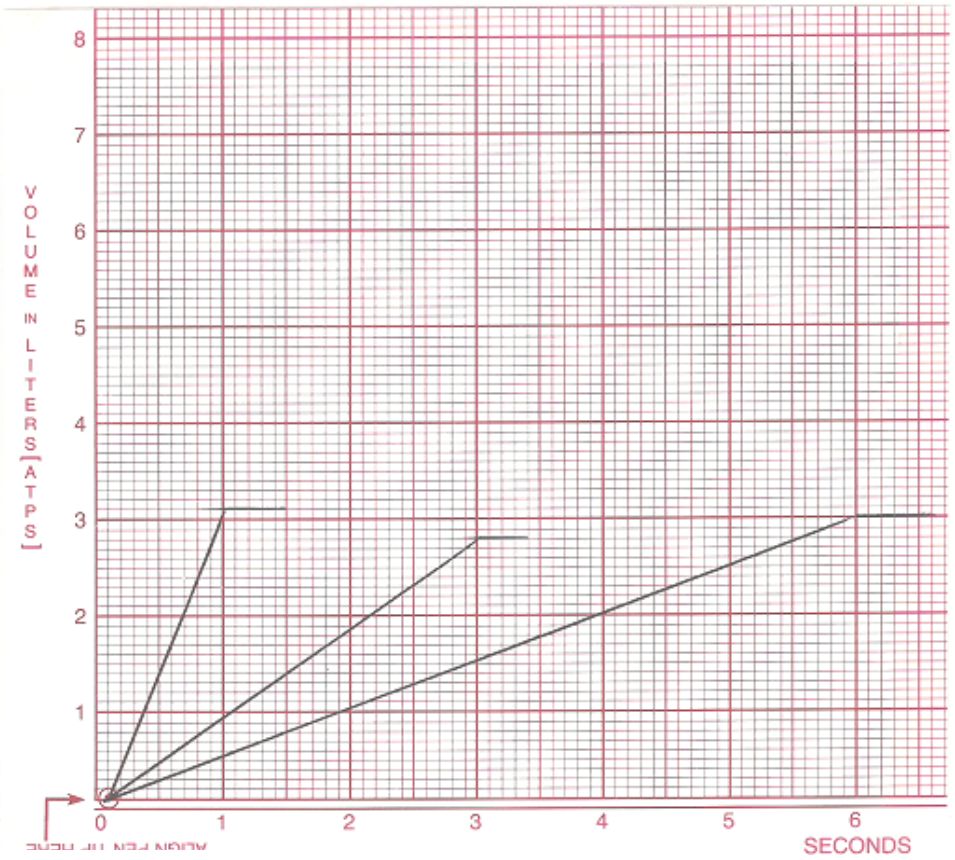
c. **Complete Calibration Exercise -on next page**

What to do if Spirometer Calibration is out

Volume Spirometer:
If the calibration is less than 2.91L, check the connection between the hose and the syringe to insure air tightness. Next, conduct a total system leak test by using a rubber stopper to occlude the spirometer If a leak is demonstrated, occlude the spirometer port and repeat the leak test. If no leak is apparent, the leak is in the hose, so it should be replaced. If a leak is still present, it is located in the spirometer. If the calibration issue is not resolved, do not test and call for service on the spirometer. If the calibration reads higher than 3.09 Check syringe to insure that, if equipped with an adjustable stop on the handle it has not moved and is in the correct position. If it is and the condition persists, call for service.

Flow Spirometer:
For flow spirometers, first check to insure there is an airtight connection between the syringe and sensor and if calibration check shows the unit to be out of calibration, steps are to be taken to inspect the sensor for debris or excessive moisture. If cleaning or replacement of the sensor does not resolve the problem, no testing should be conducted before service is performed on the system. For disposable sensors being used for calibration, they are to be replaced by new ones on a regular basis, as opposed to using the same sensor indefinitely.

5. Complete the following Calibration Exercise



PNEUMOTACH CALIBRATION REPORT

Information

Pneumotach description: SYSTEM
Pneumotach ID: 0-2121-1D73-16C7-1377-2131-1CD3-1633-1303-2-2C69

Pneumotach calibration date/time: 08/11/98 11:51 AM
Pneumotach calibration expected volume (L): 3.00
Pneumotach calibration actual volume (L): 3.03

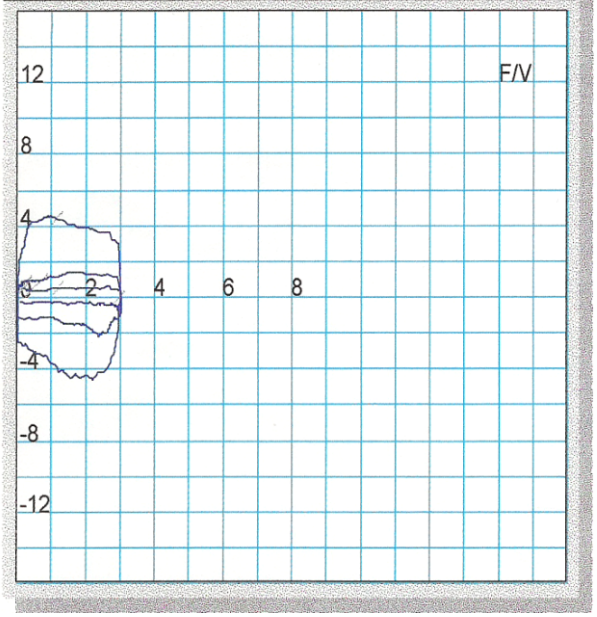
Room temperature (deg C): 24.0
Barometric pressure (mm Hg): 760.0
Relative humidity (%): 50.0

Number of efforts performed: 3
Pneumotach calibrated by: AP

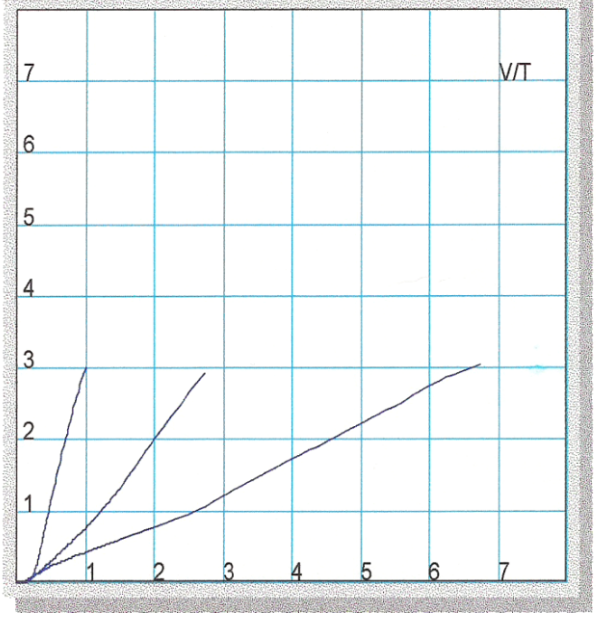
Results

Result	Expd	Meas	%Expd	Meas	%Expd	Meas	%Expd
FVC (L)	3.00	3.05	101.7%	3.03	101.0%	3.00	100.0%
PEFR (L/s)	---	0.71	---	1.45	---	4.56	---
FEF25-75% (L/s)	---	0.49	---	1.26	---	4.14	---
FIVC (L)	3.00	2.94	98.0%	3.01	100.3%	2.98	99.3%

Calibration Flow vs. Volume



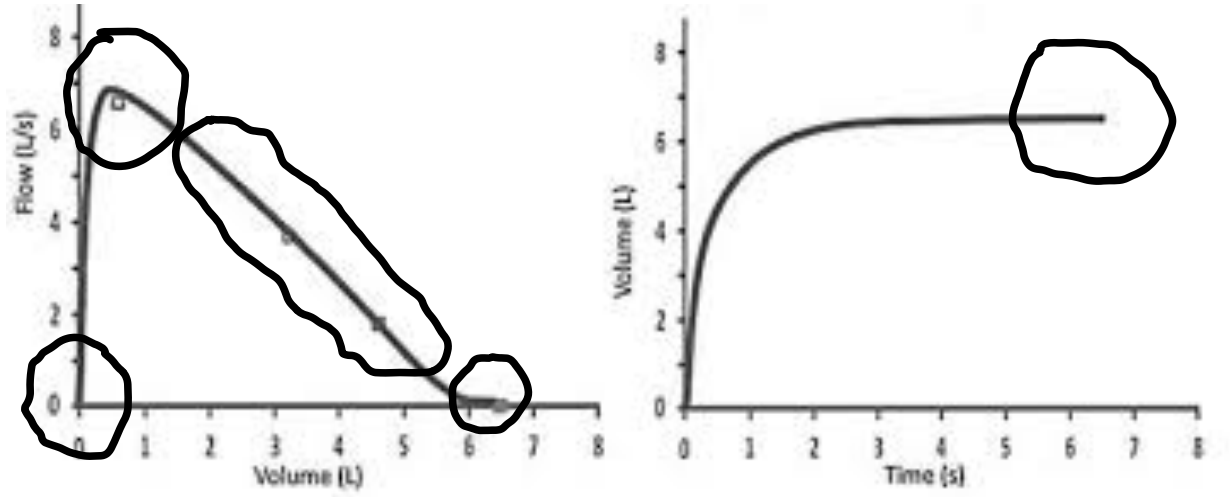
Calibration Volume vs. Time



Chapter 4

SPIROGRAM QUALITY CONTROL

SPIROGRAM PATTERNS & MORPHOLOGIES



After every maneuver, ask the following 4 questions to yourself to determine Acceptability while looking at the Flow-Volume display:

1) Is this a good start? (No hesitation, no slow start)

2) Is this a good effort? (No Submaximal effort)

3) Is there any coughing or irregularities on the downslope?

4) Is this a good finish or landing? (No abrupt termination). This question of a good finish can be more easily and definitively determined by looking at the other display…the Volume – Time display and checking to see if they met EOFE (a 1 second or greater plateau)

Normal Spirogram

When viewing the Flow Volume curve, the initial expiratory effort (after a maximal inhalation) results in a rapid rise in flow velocity to a Peak Flow maximum (sharp peak) followed by an artifact known as "critical flow point". This marks the end of the "effort dependent" Phase 1 of the curve and the transition into the "effort independent" Phase 2 where airflow becomes regulated. This phase will be highly repeatable when the subject continues to blow with maximum effort and it contains information about any obstruction that may be present. Phase 3 known as "terminal leakage flow" is a period of low flow rates caused by the asynchronous emptying of the alveoli when the subject is being urged to "blow every last bit of air out". Unfortunately, Phase 3 is not always discernable on a spirographic record due to premature termination of the effort.

In summary, a normal spirogram is marked by the onset of a sharp high peak flow, followed by a sharply declining phase 2 flow, descending at an angle of approximately 45 degrees (if healthy/normal) measured at the point representing the end of phase 2, followed by a low flow segment ending at the FVC. On the Volume-Time Curve, it is seen as a sharply rising curve with time, terminating in a 1 second plateau. Keep in mind, that for children under 6 years of age, and for all those who are over 6 years of age, there is no requirement for a minimum FET (forced expiratory time).

Operators should obtain **ACCEPTABLE** tests. Acceptable is the term we use for **GOOD** tests meaning that the test was performed properly with no errors.

An **ACCEPTABLE** test consists of the following:

- Good start (deepest breath, mouthpiece in mouth quickly, seal tightly, BIG BLAST out-hard and fast with maximal effort)
- Smooth, continuous exhalation with proper posture (upper torso upright, chin up)
- Satisfactory **EOFE** (End of Forced Exhalation)- a greater than "one second plateau" on the volume-time curve.

Two types of errors can invalidate the spirometry test. The first type is called an **ACCEPTABILITY** error. These are concerned with the Integrity of the expiratory maneuver. When these are detected, you should re-instruct the subject and repeat the test.

ACCEPTABILITY ERRORS:

A correctly executed Spirogram has 3 distinct phases, and **are without**:

1. **Slow Start (Extrapolated Volume Error)**
2. **Coughing during the first second**
3. **Premature termination of effort (phase 3 or 1 second plateau absent)**
4. **Extra Inhalations/Hesitations/Valsava Maneuver**
5. **Leaks around the mouthpiece**
6. **Obstructed mouthpiece**
7. **Evidence of an extra breath being taken during the maneuver**

The **goal during testing is to obtain 3 trials without any of the 7 conditions listed**. This is considered an **Acceptable** trial. If the curve meets conditions 1 and 2 only but fails the other five Acceptability criteria, it may be considered **Usable.** However, efforts to obtain three **Acceptable** trials should be continued up to a maximum of eight trials. **Usable** trials, where possible, must be accompanied by a slow Vital Capacity to obtain a valid vital capacity.

The second type of error concerns **REPEATABILITY**. Repeatable tests give VALIDITY to the test. Of 3 (or more) acceptable tests, the largest and second largest FVC measurements need to be within 150 mls of each other. The same rule applies to the largest and second largest FEV_1 measurements.

REMEMBER, FIRST APPLY THE ACCEPTABILITY CRITERIA THEN CHECK FOR REPEATABILITY.

Repeatability Criteria

Once you've determined you've got at least 3 Acceptable tests, the next step is to determine whether or not you've met the Repeatability Criteria.

The second type of error concerns REPEATABILITY. Repeatability errors mean that the like volumes aren't close to each other indicating that the data may not be reliable. Meeting the repeatability criteria gives VALIDITY to the test results. To meet repeatability requirements…of 3 (or more) acceptable tests, the largest and second largest FVC measurements must be within 150 mls of each other. The largest and second largest FEV_1 measurements must also be within 150 mls of each other.

Example:

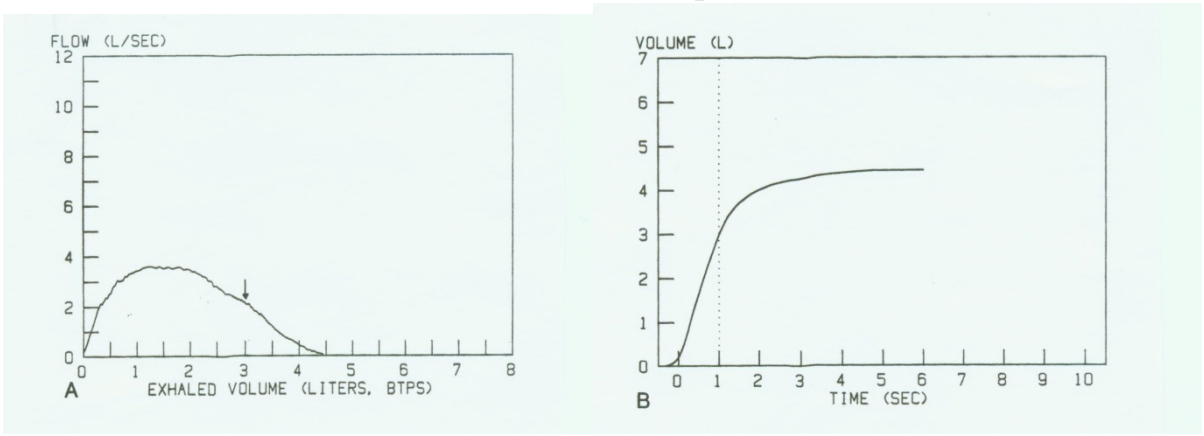
Test	FEV_1	FVC	
#1	**3.31**	**4.49**	
#2	**3.30**	**4.54**	
~~**#3**~~	~~**3.40**~~	~~**4.56**~~	(This test was determined Unacceptable because it had a slow start…we can't use it)
#4	**3.42**	**4.63**	

Which are the two largest FEV_1 volumes? 3.42 from test #4 and 3.31 from test #1. Do the math…3.42 minus 3.31=.11 (L). Convert .11 (L) into mls by multiplying by 1000 or move the decimal place over 3 places to the right. You will get 110 mils. 110 mls is the volume difference between the 2 highest FEV_1 measurements. This difference of 110 mls is less than the max allowable of 150mls, so we have met the repeatability criteria for the FEV_1 measurement.

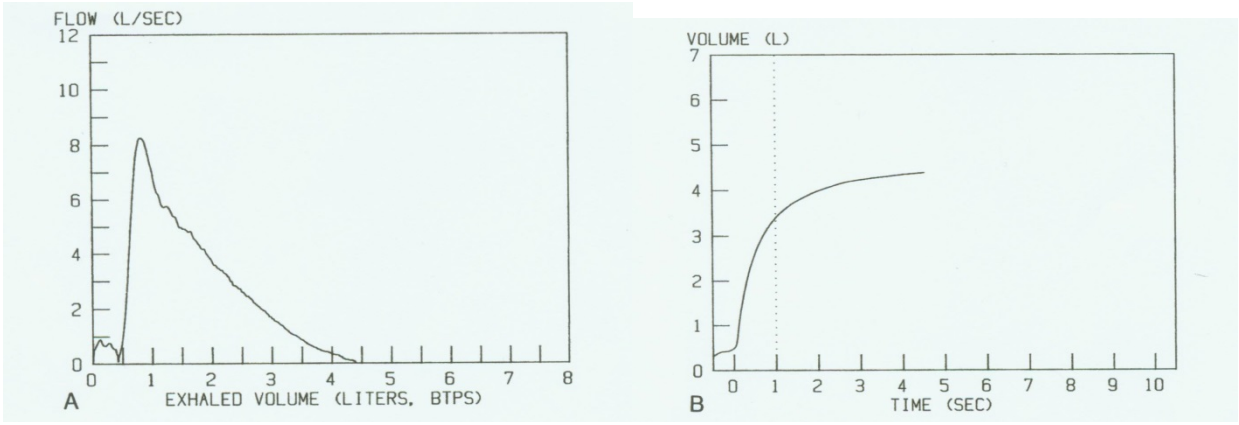
The same exercise needs to be done for the two highest FVC measurements. FVC #4, 4.63 (L) less FVC # 2, 4.54 (L). 4.63 minus 4.54= .09 **(L)** which equates to 90 mls**.** We've met repeatability for both the FEV_1 and the FVC measurements.
Remember…repeatability is all about comparing like measurements, not like tests/maneuvers. Each test/maneuver has a FEV_1 and a FVC. We look at the highest FEV_1's from each test and look at the highest FVC's from those same tests. The two highest of each like measurements need to be close to each other…how close? Within 150 mls or less.

ACCEPTABILITY ERROR EXAMPLES

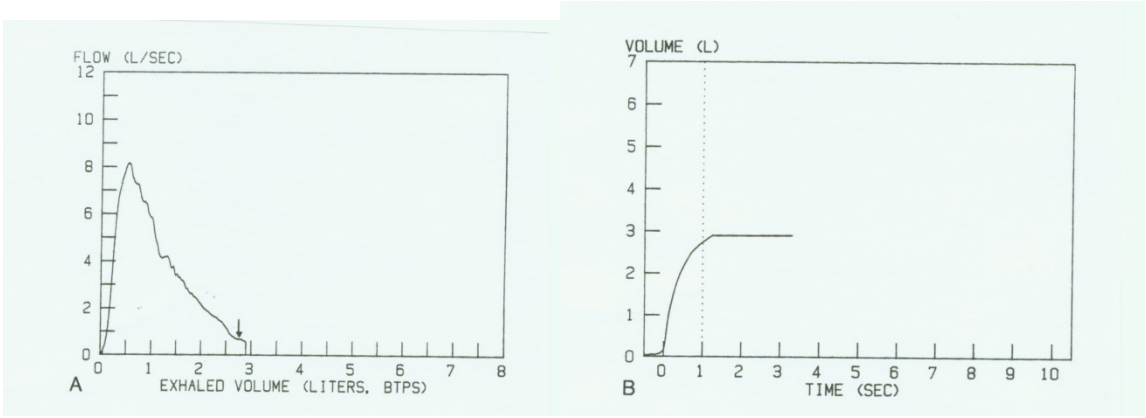
Sub-Maximal Effort – reinstruct to - take in Deepest Breath and Blast out hard & fast



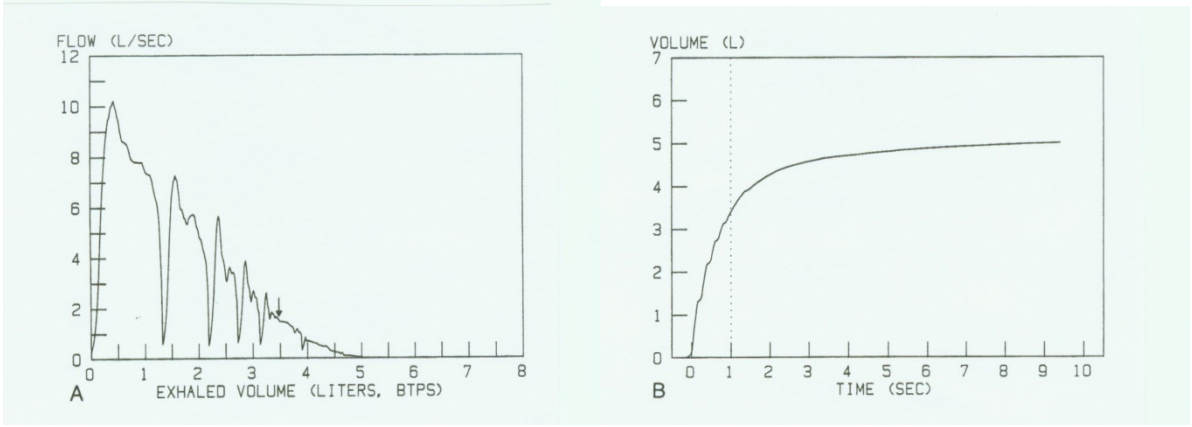
Poor Effort – reinstruct to Blast out immediately, hard and fast in one explosive exhalation, then continue exhaling with effort.



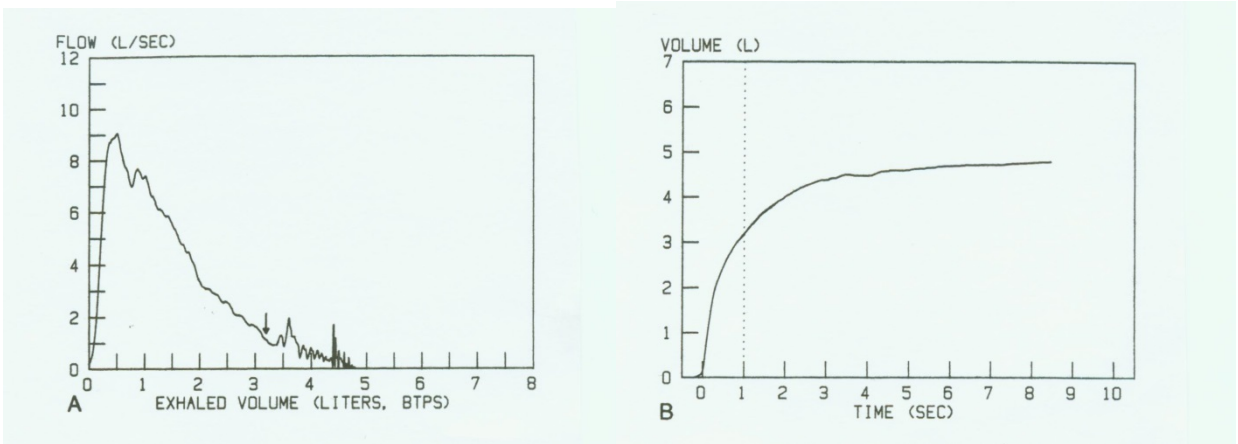
Premature Termination or Glottis Closure– reinstruct to – Continue effort for 6 seconds or until all air is out. Keep blowing until told to stop



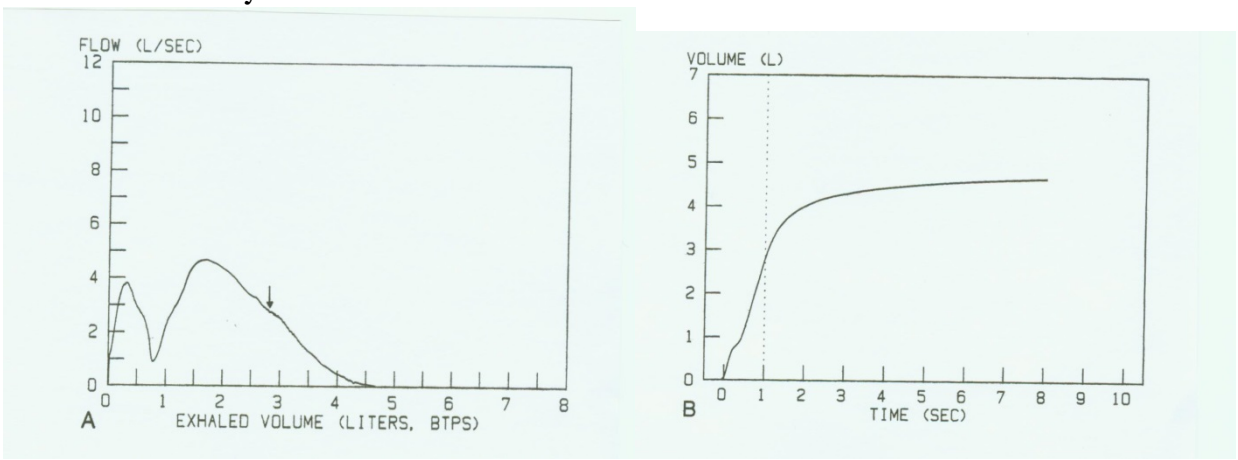
Coughing (Beginning of Test) – reinstruct to – try not to cough until after one second. Allow more time between trials. Offer a glass of water to subject



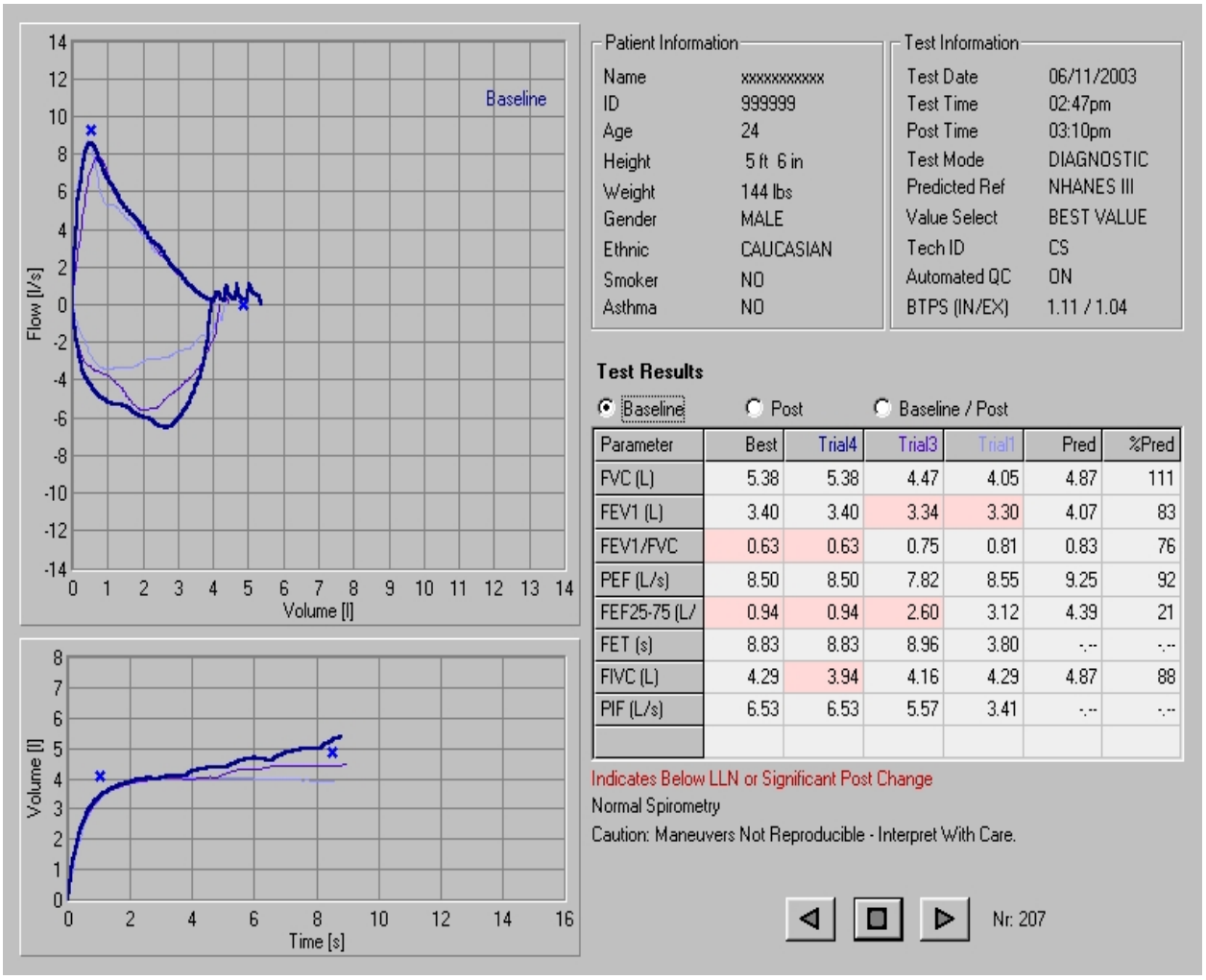
Coughing (End of Test) – reinstruct to – if needed, continue to cough through to full expiration. Although not desirable, can give a useable trial

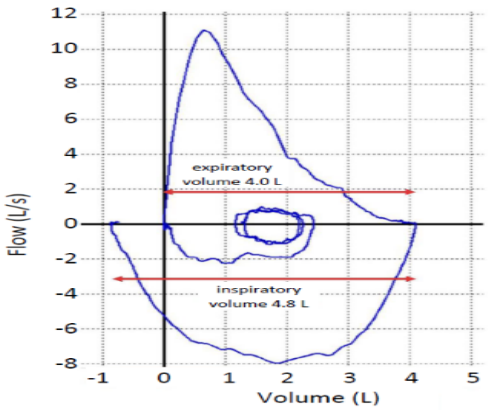


Hesitation or cough in first second – reinstruct to – blast hard and continue the expiratory effort without any hesitation

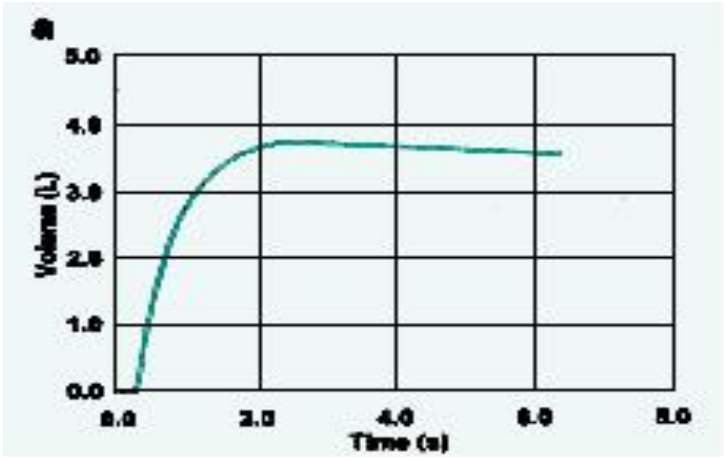


Extra Breath – reinstruct to – exhale in one continuous breath with no inhalations. If necessary, use a nose clip or manually occlude the nose





For a FVL display, it is unacceptable for the FIVC – FVC > 0.100L or 5% of the FVC, whichever is greater.



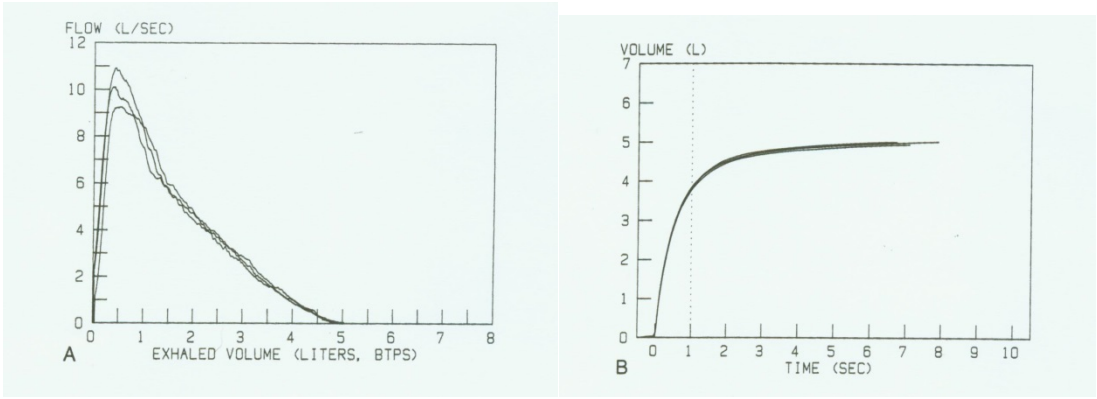
Leak (in Volume Type Spirometer)

Or a Negative Zero Flow Error Check
in a Flow Spirometer

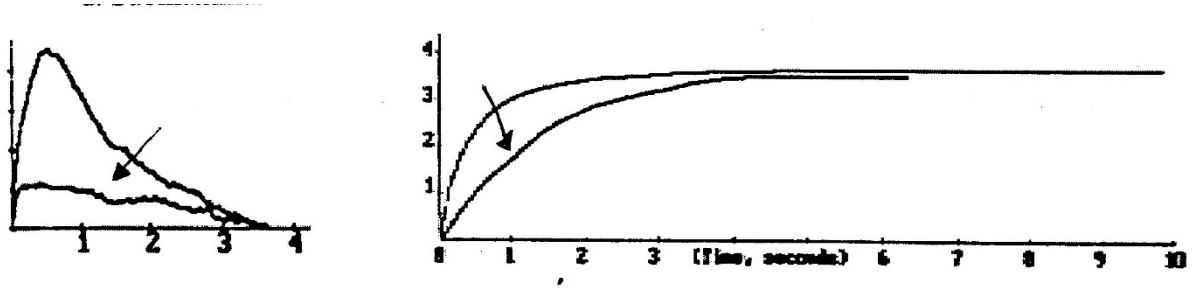
REPEATABILITY REQUIREMENT

Normal Spirograms showing Test Repeatability

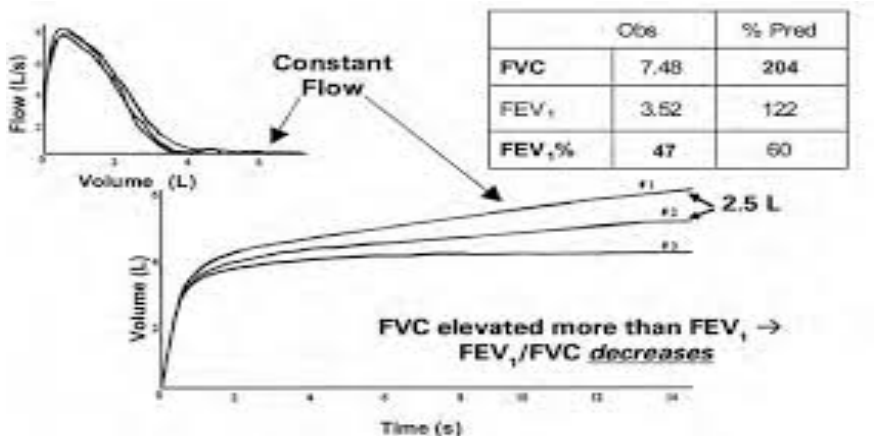
The two best FVC & FEV_1 measurements must repeat within 150ml.



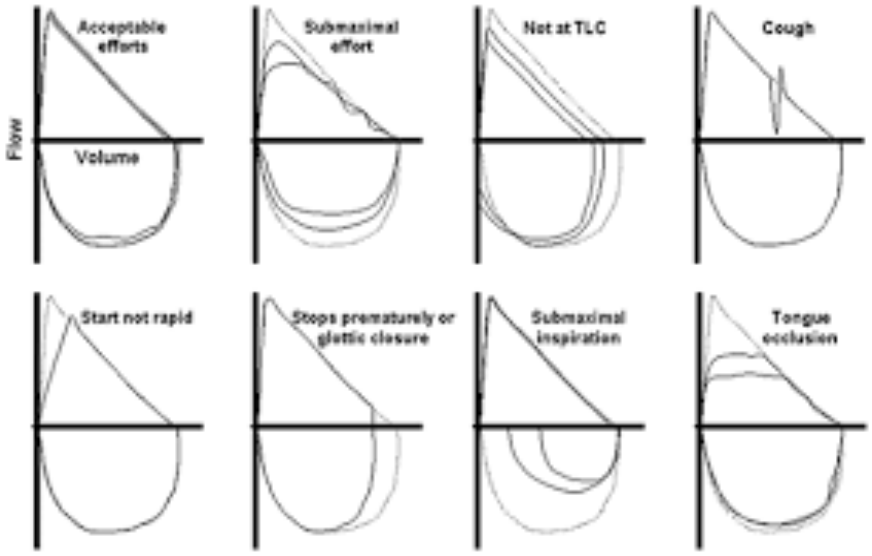
Mouthpiece obstruction – put mouthpiece on top of tongue to prevent the blocking of air flow.



Positive Zero flow – during the zeroing process, do not move mouthpiece / sensor.



Flow Volume Loop Acceptability Errors



THE NEED FOR A COMPREHENSIVE QUALITY ASSURANCE PROGRAM

BENEFITS

The purpose of instituting a respiratory health surveillance program is to provide a mechanism to identify and track small changes in function which may be indicative of developing pathology. In so doing, it provides an opportunity for medical management to intervene and change the course of the developing health effect and to relate changes to specific times and rates of exposures. From these findings, personal protection or production procedures can be modified to reduce company risk and improve health and safety.

To maintain the sensitivity and specificity of the surveillance program, data collection must be impeccable, and remain so for the course of the surveillance. Otherwise discrete changes in function are lost in the testing noise that ensues from poor data collection. The over reading physician may be faced with reading an invalid record or miss the borderline or abnormal finding.

Another variable that can affect test accuracy is testing noise which can come from one of two sources: Technical & Biologic.

1. Technical

Equipment Performance Specifications
Equipment Calibration
Test Procedures (# of trials, quality of coaching)
Posture During the Test
Quality of Subject Effort
Technician - Subject Interactions
Ambient Temperature, Barometric Pressure
Software Quality

2. Biologic

Diurnal-Seasonal Variation
Race (12%)
Sex
Age, Height
Weight (Obesity)
Smoking Hx, Respiratory Hx, Occupation, Air Pollution

COMPONENT PARTS

To control data quality, a three- point quality assurance program should be overlaid across the data collection. The elements of the program are as follows:

- **NIOSH Approved Training of all professionals engaged in spirometry data collection, followed by periodic retraining.** In occupational medicine, the consequences of misinterpretations can go beyond simply making an inaccurate diagnosis. It affects decisions regarding fitness for duty, workplace accommodation, and compensation for work-related illness. Furthermore, since occupational spirometry tests are often conducted in the regulatory and medical-legal arenas, the validity of the spirometry test are likely to be scrutinized. Therefore, it is critical for both clinical and administrative purposes that occupational medicine physicians understand the need for standardization and quality control in spirometry.

- **Written Standard Operating Procedures (SOP) which are necessary to harmonize data collection between nurses and all sites. This becomes the program blueprint.**

  - The basic objective of a Standard Operating Procedures manual is to unify and promote superior quality spirometry data collection between all personnel responsible for collecting spirometry data and between all sites where data is collected. Data excellence increases the test sensitivity and specificity.

  - The SOP manual is written around the current spirometry equipment being used by a company, and serves as a final authority on questions pertaining to:

    Test procedures
    Calibration Requirement
    Quality Control Elements
    Sterilization and Cleaning Procedures and Periodicity
    Data Disposition and Record Keeping

  - Information on all these points can be found in the OSHA Document (Gold Section) for SOP outline pages 54-55.

  - An SOP represents a blueprint of the testing program and is the foundation of any Quality Control Program. It not only serves as an internal trouble-shooter and argument resolver, but provides documentation in case of legal, clinical or regulatory enquiries.

In summary, the steps outlined are based upon the premise that **"Superior quality is directly related to Conforming to Established Procedures"** (as written in the SOP and practiced during training) Conversely, **"Deviation from procedures constitutes poor test quality"** leading to poor data and consequently, the failure of the Surveillance Program. (Quality without Tears. Phil. B. Crosby, 1984; McGraw Hill)

QC REVIEW

The ATS 1994 Update recommends that spirometry data collection programs be subject to a Quality Control review to insure the continued collection of valid data. The basis for this recommendation stems from the National Lung Health Study which demonstrated that a consistently applied Quality Control Program resulted in a significantly higher yield of valid data.

Since data validity results in increased test sensitivity and specificity, it follows that any screening and surveillance program using Quality Control will reduce its risk of obtaining false positive and negative data. The program requires a sample of spirometry records be reviewed on a periodic basis for review and evaluation. Consistent procedural errors that invalidate the data can be identified with corrective measures suggested to that technician.

The basic document around which all Quality Control decisions are made is a written **Standard Operating Procedure Manual (SOP)**. This document provides a blueprint for standardizing test procedures between personnel and various sites. Such guidelines increase the sensitivity and specificity of the program.

Table 10. Grading System for FEV1 and FVC (Graded Separately)

Grade	Number of Measurements	Repeatability: Age >6 yr	Repeatability: Age ≤6 yr
A	≥3 acceptable	Within 0.150L	Within 0.100L
B	2 acceptable	Within 0.150L	Within 0.100L
C	≥2 acceptable	Within 0.200L	Within 0.150L
D	≥2 acceptable	Within 0.250L	Within 0.200L
E	≥2 acceptable	>0.250L	>0.200L
	OR 1 acceptable	N/A	N/A
U	0 acceptable AND ≥ 1 usable	N/A	N/A
F	0 acceptable and 0 usable	N/A	N/A

Definition of abbreviation: N/A = not applicable. The repeatability grade is determined for the set of prebronchodilator maneuvers and the set of post-bronchodilator maneuvers separately. The repeatability criteria are applied to the differences between the two largest FVC values and the two largest FEV1 values. Grade U indicates that only usable but not acceptable measurements were obtained. Although some maneuvers may be acceptable or usable at grading levels lower than A, the overriding goal of the operator must be to always achieve the best possible testing quality for each patient.

As stated in the 2019 ATS Spirometry Update, "Technical standards are designed to help attain the best result possible for each patient. Spirometry results are very dependent on patient cooperation. Maneuvers done at maximal lung volume with maximal effort are more repeatable than maneuvers that are done at submaximal lung volumes or with submaximal effort."

The grading system will inform the interpreter about the level of confidence that the spirometry results represent the best that the patient was able to do at the time of the test. Some patients will not be able to meet the repeatability or acceptability criteria to get an "A" grade, but their results may be clinically useful.

Keep in mind that although the maneuvers may not reach an "A" grade, the GOAL of the operator must always be to achieve the best possible testing quality for each patient. Remember, the grading system is for the operator and has nothing to do with the patient's health. The grade is to show the consistency in the patient's blows.

Chapter 5

HOW TO PERFORM SPIROMETRY?

SPIROMETRY SIX STEP TEST PROCEDURE LIST

Spirometry testing is simple but fraught with technical pitfalls that can invalidate the pulmonary function measurements. Failure to obtain full understanding, cooperation and effort from a subject during any part of the test usually results in an underestimation of the true pulmonary function. Poorly maintained spirometers also affect the accuracy of observed spirometric values. Such erroneous measurements may cause a normal, healthy subject to be mislabeled as impaired or lead to incorrect assessments of impaired subjects. When evaluating changes over time, small decrements in pulmonary function may be lost in the noise of the measurements if testing equipment and/or techniques are not as accurate, precise, rigorous, and standardized as possible. For analysis of group data, small differences between groups, which may be scientifically important, can be obscured by poor quality data caused by inadequate testing technique.

In occupational medicine, the consequences of such misinterpretations can go beyond simply making an inaccurate diagnosis; decisions regarding fitness for duty, workplace accommodation, and compensation for work-related illness may also be affected. Furthermore, since occupational spirometry tests are often conducted in the regulatory and medical-legal arenas, the validity of the spirometry test is likely to be scrutinized. Therefore, it is critical for both clinical and administrative purposes that occupational medicine physicians understand the need for standardization and quality control in spirometry.

(ACOEM Spirometry Position Paper.2000)

SUMMARY OF SIX STEPS TEST PROCEDURE

1. **Establish rapport**
2. **Gather pre-test data: Pre-screen questionnaire, B.P., height, BMI**
3. **Two Explanations: [a] Briefly explain test; [b] Explain mouthpiece position**
4. **Three Demonstrations:[a](Technician) Demonstrate mouthpiece position; [b] Have test Subject demonstrate mouthpiece position; [c] (Technician) Demonstrate test with maximal effort blast**
5. **Administer Test: Chin up & chair behind, torso upright, mouthpiece off to side, coach to full inspiration, BLAST OUT, & full expiration.**
6. **Look for acceptability then repeatability.**

LANGUAGE (SCRIPT) TO ADMINISTER A SPIROMETRY TEST

"Hi, my name is _____. So, you are here for your lung function test. Have patient sanitize their hands.(Before we get started, I need to ask you a few questions to see if we can continue." (ask pre-screen questions and write proper notes to positive responses) Postpone testing if necessary.

Explanation for the FVC:
"Let me briefly explain what I will be asking you to do. You will need to take the deepest, deepest, breath that you can possibly take, put the mouthpiece in your mouth, and then BLAST the air out hard and fast, and keep going until I tell you to stop."

Explanation for the FVL – Flow Volume Loop:
"Let me briefly explain what I will be asking you to do. With a nose clip on, you will insert the mouthpiece on top of your tongue and seal your lips tightly around it. You will take 3 normal breaths, then take the deepest, deepest breath that you possibly can, and BLAST out the air hard and fast. When I tell you to, you will then take in a full inspiration".

"But first, let me explain to you how to use the mouthpiece. Lay the tube on your tongue, like a tongue depressor, and wrap your lips tightly around it."

- **Demonstrate Mouthpiece Placement: "It looks like this".** Demonstrate using your hand as a tongue.

"Now, can you show me"? Have subject demonstrate mouthpiece placement. **(Have patient put their mask back on)**

- **Now here is what the entire maneuver will look like:** "I'm going to ask you to hold your mouthpiece steady by your cheek, then take your mask down and put a nose clip on. Then you are going to take the DEEPEST, DEEPEST breath you can possibly take, put the mouthpiece in your mouth, and then BLAST the air out hard and fast and keep going and going until I tell you to stop."

Enter demographics into the spirometer at this point. **(during this time, have patient assemble their mouthpiece)**

Now get the subject ready for the test. (either in the sitting or standing position depending on your written SOP)

"We will be in the sitting position. Sit up straight, shoulders back, and chin slightly elevated. Please hold the spirometer off to the side of your cheek and hold it steady". (have patients block the end of the filter for the zeroing of the spirometer)

If you will be standing:
"We will be in the standing position. Stand up straight, shoulders back, and chin slightly elevates. There will be a chair behind you if you feel the need to sit down".

"Are you ready? Mask down, Nose clip on, Let's go! DEEP, DEEP, tube in, BLAST!! Keep going, keep going, keep going….. squeeze…. and stop".
(Have patient take their nose clip off and put their mask back on)

For the FVL: - with the nose clip on and tube on top of their tongue:
"Take in a deep deep breath, and BLAST it out! Keep going…keep going… (operator looks for the 1 second plateau to be met), now BIG INHALATION.

Other tips:

Due to the "learning curve" it usually requires several attempts to achieve the optimal spirogram. First obtain three maneuvers. If satisfactory data has not been obtained after three attempts, rest the employee and then do up to five more maneuvers, for a total of eight.

- Before commencing the first maneuver the employee should have the mouthpiece firmly seated in the spirometer hose or sensor and both hands around the hose just below the mouthpiece holder or sensor. Instruct to hold the sensor still to the side of mouth to prevent any airflow through the sensor thereby either preventing the spirometer establishing a true "zero" or reads the air movement as a "false blow".
- If standing, stand erect with chin slightly elevated and place a sturdy chair behind the subject. If sitting, sit erect at the front edge of the chair with chin slightly elevated. If using a nose clip, apply it at this point.
- Ask if it is okay to touch their shoulder as a reminder to remain upright if they start to bend over

- A maximal inhalation is rapidly taken from room air before placing the mouthpiece in the mouth. Prompt the inhalation with statement such as "Deep, deep".
  (Watch to make sure that their mouth is tightly closed around the mouthpiece.)
- Then prompt the exhalation with: "Now **BLAST**!!!"

- Be a cheerleader. Don't be shy. Show energy in your voice. Your enthusiastic coaching makes a significant difference in the effort the employee will make. (You are the primary stimulus, which controls the subjects' response). You need not shout but have intensity in your voice.

- Continue coaching until a one second plateau is observed.

Review spirogram for Acceptability or Repeatability errors. If present, reinstruct the subject and continue testing.

Flow-Volume Loop Procedure:

Though the FVL is commonly used in clinical testing, the ATS/ERS confirms that expiration only and expiration-inspiration techniques both meet the recommendations of the 2019 ATS/ERS Spirometry statement.

Based on the information above, it is perfectly acceptable to perform spirometry in occupational settings using either the FVC (expiration only) or FVL (expiration-inspiration).

For spirometers that measure inspiration and expiration, there are four distinct phases of the FVC maneuver: **1**) maximal inspiration, **2**) a "blast" of expiration, **3**) continued complete expiration for a maximum of 15 seconds, and **4**) inspiration at maximal flow back to maximum lung volume. Most of the variability in results obtained from spirometry relates to inadequate and variable inspiration to TLC, ending the expiration prematurely, and variable effort. See table 6 on the next page.
You must keep in mind that since the 2019 Update Standard requirement for FET (forced Expiratory time) has been eliminated, increased vigilance and training by the operator and interpreter are required in the assessment of whether expiration was complete or there was early termination.

If the volume of the maximal inspiration (i.e., FIVC) after EOFE is greater than FVC, then the patient did not start the maneuver from TLC. FEV1 and FVC measurements from a maneuver with
FIVC - FVC >0.100 L or 5% of FVC, whichever is greater, are not acceptable.

Table 6. (page e78 in ATS – Standardization of Spirometry 2019 Update)

Procedures for FVC Maneuvers

Wash hands* (or use an approved hand sanitizer)

Prepare the patient
Dispense hand sanitizer for the patient
Confirm patient identification, age, birth sex, ethnicity, etc.
Measure weight and height without shoes
Ask about activities listed in Table 5, medication use, and any relative contraindications flagged on the requisition; note respiratory symptoms

Instruct and demonstrate the test
Position of the mouthpiece and nose clip
Correct posture with head slightly elevated
Inspire rapidly until completely full
Expire with maximal effort until completely empty
Inspire with maximal effort until completely full
Confirm that patient understands the instructions and is willing to comply

Perform maneuver FVL
Have patient assume the correct posture
Attach nose clip, place mouthpiece in mouth, and close lips around the mouthpiece
Breathe normally
Inspire completely and rapidly with a pause of ≤ 2 s at TLC
Expire with maximal effort until no more air can be expelled while maintaining an upright posture
Inspire with maximal effort until completely full
Repeat instructions as necessary, coaching vigorously
Repeat for a minimum of three maneuvers, usually no more than eight for adults
Check FEV1 and FVC repeatability and perform more maneuvers as necessary

Perform maneuver (expiration-only devices) FVC
Have patient assume the correct posture
Attach nose clip
Inspire completely and rapidly with a pause of ≤2 s TLC
Place mouthpiece in mouth and close lips around the mouthpiece
Expire with maximal effort until no more air can be expelled while maintaining an upright posture
Repeat instructions as necessary, coaching vigorously
Repeat for a minimum of three maneuvers, usually no more than eight for adults
Check FEV1 and FVC repeatability and perform more maneuvers as necessary

*Additional steps may be required by local infection control policies. Using disposable gloves does not eliminate the need for hand washing or sanitizing, but if gloves are used, a new pair is required for each patient.

BE A GOOD OBSERVER

Poor maneuvers can be recognized by watching the employee perform them. Good maneuvers require: an adequate understanding, maximal inhalation, a rapid start of the effort, and maximal effort until a 1 second plateau is reached. Unacceptable conditions include: a slow or hesitating start, air leaking around the mouthpiece, inhalations or hesitations or the premature termination of the maneuver. When these occur reinstruct the employee and repeat the trial. Some employees refrain from exhaling the maximum amount because it results in coughing or causes discomfort. Allow them to drink some water, rest and then try again. Sometimes you may encounter an employee who just cannot seem to produce acceptable maneuvers. This may be very frustrating for both of you. When this occurs, rest the subject, reinstruct and retry the test sequence. Sometimes the problem can be resolved by having a different operator administer the test. Do not continue with the test if the subject appears to be having difficulty or marked discomfort.

Table 5. (page e77 in ATS – Standardization of Spirometry 2019 Update)

Activities That Should Be Avoided before Lung Function Testing

Smoking and/or vaping and/or water pipe use within 1 h before testing (to avoid acute bronchoconstriction due to smoke inhalation)
Consuming intoxicants within 8 h before testing (to avoid problems in coordination, comprehension, and physical ability)
Performing vigorous exercise within 1 h before testing (to avoid potential exercise-induced bronchoconstriction)
Wearing clothing that substantially restricts full chest and abdominal expansion (to avoid external restrictions on lung function)

See sample prescreen questionnaire on the following page. These questions should be asked by the operator prior to the spirometry test and should be part of the documents given to the Over Reader. All these questions could either increase or decrease the results at the time of the test, or even prohibit you for testing the subject in the first place.

PRESCREENING QUESTIONS

Completed by Certified Spirometry Operator *Prior* to Testing and Attached to the Spirometry Record.

Name (last, first): _____ Company:_____

ID# _____

Yes No 1. In the last 6 weeks have you had a chest injury or surgery involving the eye, ear, chest, abdomen, have been diagnosed with an aneurysm or been hospitalized for a heart attack ?
If Yes:
1a. Do not test at this time. Reschedule spirometry test for 6 weeks or get treating physician's approval.

Yes No 2. Are you under a physician's care for high blood pressure?
If Yes:
2a. If blood pressure exceeds action level, obtain Physician clearance before proceeding.

Yes No 3. Within the last hour have you smoked or vaped?
If Yes:
3a. to smoking, if possible, wait one hour before testing, otherwise make a notation over reader and proceed.

Yes No 4. Within the last hour have you eaten a full meal? (you know, like a big Thanksgiving meal?)
If Yes:
4a. to eating, if possible, wait one hour before testing, otherwise make notation to over reader and proceed.

Yes No 5. Have you had a respiratory infection (such as flu, pneumonia, bronchitis, chest cold, or Covid) in the last 3 weeks?
If Yes:
5a. Postpone testing until 3 weeks after symptoms resolve.

Yes No 6. Have you used an emergency inhaler the last 6 hours? (postpone if used)

Yes No 7. Have you had more than 2 cups of caffeinated coffee, tea, energy drinks, Cola, or caffeine pills, (total) in the last 6 hours?
If Yes:
7a. If possible, wait one hour before testing, otherwise make notation to over reader and proceed.

Yes No 8. Are you wearing any tight or restrictive clothing? If so, you might want to loosen up at this time.

Yes No 9. Are you wearing dentures?

Today's Measurements

Height: __ __ Inches (measured by standiometer) Weight: __ __ __ Pounds (measured by scale)

BP (mmHg) ___/____ ____/____ ____/____

(If measurement falls exactly on the half inch, or half pound, round odd numbers down and even up).
Certified spirometry technician's initials or ID #: _____ Date: _____ - _____20__

BLOOD PRESSURE CLASSIFICATION CHART

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120 – 129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130 – 139	or	80 – 89
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120

Classification of Blood Pressure for Adults 18 Years and Older

American Heart Association (2017)

The medical director of the facility should establish Cut off Criteria for Blood Pressure for spirometry evaluations. If exceeded, clear with a physician before proceeding with the test.

OSHA Medical Clearance Questionnaire

(Appendix C to Sec. 1910.134: OSHA Respirator Medical Evaluation Questionnaire (Mandatory)

To the employer: Answers to questions in Section 1, and to question 9 in Section 2 of Part A, do not require a medical examination.

To the employee:

Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

Part A. Section 1. (Mandatory) The following information must be provided by every employee who has been selected to use any type of respirator (please print).

1. Today's date:_____

2. Your name:_____

3. Your age (to nearest year):_____

4. Sex (circle one): Male/Female

5. Your height: _____ ft. _____ in.

6. Your weight: _____ lbs.

7. Your job title:_____

8. A phone number where you can be reached by the health care professional who reviews this questionnaire (include the Area Code): _____

9. The best time to phone you at this number: _____

10. Has your employer told you how to contact the health care professional who will review this questionnaire (circle one): Yes/No

11. Check the type of respirator you will use (you can check more than one category):
a. _____ N, R, or P disposable respirator (filter-mask, non-cartridge type only).
b. _____ Other type (for example, half- or full-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus).

12. Have you worn a respirator (circle one): Yes/No

If "yes," what type(s):_____

Part A. Section 2. (Mandatory) Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator (please circle "yes" or "no").

1. Do you *currently* smoke tobacco, or have you smoked tobacco in the last month: Yes/No

2. Have you *ever had* any of the following conditions?

a. Seizures: Yes/No

b. Diabetes (sugar disease): Yes/No

c. Allergic reactions that interfere with your breathing: Yes/No

d. Claustrophobia (fear of closed-in places): Yes/No

e. Trouble smelling odors: Yes/No

3. Have you *ever had* any of the following pulmonary or lung problems?

a. Asbestosis: Yes/No

b. Asthma: Yes/No

c. Chronic bronchitis: Yes/No

d. Emphysema: Yes/No

e. Pneumonia: Yes/No

f. Tuberculosis: Yes/No

g. Silicosis: Yes/No

h. Pneumothorax (collapsed lung): Yes/No

i. Lung cancer: Yes/No

j. Broken ribs: Yes/No

k. Any chest injuries or surgeries: Yes/No

l. Any other lung problem that you've been told about: Yes/No

4. Do you *currently* have any of the following symptoms of pulmonary or lung illness?

a. Shortness of breath: Yes/No

b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No

c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No

d. Have to stop for breath when walking at your own pace on level ground: Yes/No

e. Shortness of breath when washing or dressing yourself: Yes/No

f. Shortness of breath that interferes with your job: Yes/No

g. Coughing that produces phlegm (thick sputum): Yes/No

h. Coughing that wakes you early in the morning: Yes/No

i. Coughing that occurs mostly when you are lying down: Yes/No

j. Coughing up blood in the last month: Yes/No

k. Wheezing: Yes/No

l. Wheezing that interferes with your job: Yes/No

m. Chest pain when you breathe deeply: Yes/No

n. Any other symptoms that you think may be related to lung problems: Yes/No

5. Have you *ever had* any of the following cardiovascular or heart problems?

a. Heart attack: Yes/No

b. Stroke: Yes/No

c. Angina: Yes/No

d. Heart failure: Yes/No

e. Swelling in your legs or feet (not caused by walking): Yes/No

f. Heart arrhythmia (heart beating irregularly): Yes/No

g. High blood pressure: Yes/No

h. Any other heart problem that you've been told about: Yes/No

6. Have you *ever had* any of the following cardiovascular or heart symptoms?

a. Frequent pain or tightness in your chest: Yes/No

b. Pain or tightness in your chest during physical activity: Yes/No

c. Pain or tightness in your chest that interferes with your job: Yes/No

d. In the past two years, have you noticed your heart skipping or missing a beat: Yes/No

e. Heartburn or indigestion that is not related to eating: Yes/No

d. Any other symptoms that you think may be related to heart or circulation problems: Yes/No

7. Do you *currently* take medication for any of the following problems?

a. Breathing or lung problems: Yes/No

b. Heart trouble: Yes/No

c. Blood pressure: Yes/No

d. Seizures: Yes/No

8. If you've used a respirator, have you *ever had* any of the following problems? (If you've never used a respirator, check the following space and go to question 9:)

a. Eye irritation: Yes/No

b. Skin allergies or rashes: Yes/No

c. Anxiety: Yes/No

d. General weakness or fatigue: Yes/No

e. Any other problem that interferes with your use of a respirator: Yes/No

9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire: Yes/No

Questions 10 to 15 below must be answered by every employee who has been selected to use either a full-facepiece respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use other types of respirators, answering these questions is voluntary.

10. Have you *ever lost* vision in either eye (temporarily or permanently): Yes/No

11. Do you *currently* have any of the following vision problems?

a. Wear contact lenses: Yes/No

b. Wear glasses: Yes/No

c. Color blind: Yes/No

d. Any other eye or vision problem: Yes/No

12. Have you *ever had* an injury to your ears, including a broken ear drum: Yes/No

13. Do you *currently* have any of the following hearing problems?

a. Difficulty hearing: Yes/No

b. Wear a hearing aid: Yes/No

c. Any other hearing or ear problem: Yes/No

14. Have you *ever had* a back injury: Yes/No

15. Do you *currently* have any of the following musculoskeletal problems?

a. Weakness in any of your arms, hands, legs, or feet: Yes/No

b. Back pain: Yes/No

c. Difficulty fully moving your arms and legs: Yes/No

d. Pain or stiffness when you lean forward or backward at the waist: Yes/No

e. Difficulty fully moving your head up or down: Yes/No

f. Difficulty fully moving your head side to side: Yes/No

g. Difficulty bending at your knees: Yes/No

h. Difficulty squatting to the ground: Yes/No

i. Climbing a flight of stairs or a ladder carrying more than 25 lbs: Yes/No

j. Any other muscle or skeletal problem that interferes with using a respirator: Yes/No

Part B Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire.

1. In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen: Yes/No

If "yes," do you have feelings of dizziness, shortness of breath, pounding in your chest, or other symptoms when you're working under these conditions: Yes/No

2. At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals

(e.g., gases, fumes, or dust), or have you come into skin contact with hazardous chemicals: Yes/No

If "yes," name the chemicals if you know them:_____

_____

_____

3. Have you ever worked with any of the materials, or under any of the conditions, listed below:

a. Asbestos: Yes/No

b. Silica (*e.g.*, in sandblasting): Yes/No

c. Tungsten/cobalt (e.g., grinding or welding this material): Yes/No

d. Beryllium: Yes/No

e. Aluminum: Yes/No

f. Coal (for example, mining): Yes/No

g. Iron: Yes/No

h. Tin: Yes/No

i. Dusty environments: Yes/No

j. Any other hazardous exposures: Yes/No

If "yes," describe these exposures:_____

_____

_____

4. List any second jobs or side businesses you have:_____

_____

5. List your previous occupations:_____

_____

6. List your current and previous hobbies:_____

_____

7. Have you been in the military services? Yes/No

If "yes," were you exposed to biological or chemical agents (either in training or combat): Yes/No

8. Have you ever worked on a HAZMAT team? Yes/No

9. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures

mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications): Yes/No

If "yes," name the medications if you know them:_____

10. Will you be using any of the following items with your respirator(s)?

a. HEPA Filters: Yes/No

b. Canisters (for example, gas masks): Yes/No

c. Cartridges: Yes/No

11. How often are you expected to use the respirator(s) (circle "yes" or "no" for all answers that apply to you)?:

a. Escape only (no rescue): Yes/No

b. Emergency rescue only: Yes/No

c. Less than 5 hours *per week:* Yes/No

d. Less than 2 hours *per day:* Yes/No

e. 2 to 4 hours per day: Yes/No

f. Over 4 hours per day: Yes/No

12. During the period you are using the respirator(s), is your work effort:

a. *Light* (less than 200 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of a light work effort are *sitting* while writing, typing, drafting, or performing light assembly work; or *standing* while operating a drill press (1-3 lbs.) or controlling machines.

b. *Moderate* (200 to 350 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of moderate work effort are *sitting* while nailing or filing; *driving* a truck or bus in urban traffic; *standing* while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; *walking* on a level surface about 2 mph or down a 5-degree grade about 3 mph; or *pushing* a wheelbarrow with a heavy load (about 100 lbs.) on a level surface. c. *Heavy* (above 350 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of heavy work are *lifting* a heavy load (about 50 lbs.) from the floor to your waist or shoulder; working on a loading dock; *shoveling; standing* while bricklaying or chipping castings; *walking* up an 8-degree grade about 2 mph; climbing stairs with a heavy load (about 50 lbs.).

13. Will you be wearing protective clothing and/or equipment (other than the respirator) when you're using your respirator: Yes/No

If "yes," describe this protective clothing and/or equipment:_____
_____

14. Will you be working under hot conditions (temperature exceeding 77 deg. F): Yes/No

15. Will you be working under humid conditions: Yes/No

16. Describe the work you'll be doing while you're using your respirator(s):
_____
_____

17. Describe any special or hazardous conditions you might encounter when you're using your respirator(s) (for example, confined spaces, life-threatening gases):
_____
_____

18. Provide the following information, if you know it, for each toxic substance that you'll be exposed to when you're using your respirator(s):

Name of the first toxic substance:_____
Estimated maximum exposure level per shift:_____
Duration of exposure per shift:_____
Name of the second toxic substance:_____
Estimated maximum exposure level per shift:_____
Duration of exposure per shift:_____
Name of the third toxic substance:_____
Estimated maximum exposure level per shift:_____
Duration of exposure per shift:_____
The name of any other toxic substances that you'll be exposed to while using your respirator:
_____
_____
_____

19. Describe any special responsibilities you'll have while using your respirator(s) that may affect the safety and well-being of others (for example, rescue, security):
_____

CRITERIA TO SIT OR TO STAND AND BMI/ WEIGHT CHART

SIT OR STAND WEIGHT CHART

Severely overweight subjects should be required to STAND for spirometry if the customary *Standard Operating Procedure* is to sit for the test. This chart is based on NHANES II statistics (Ann Intern Med 1985; 103:983-988).

WEIGHT CHART FOR MEN						WEIGHT CHART FOR WOMEN				
HEIGHT						HEIGHT				
Ft	In	Inches	Overw eight (Pounds)	Severely Overw eight		Ft	In	Inches	Overw eight (Pounds)	Severely Overw eight
5	0	60	142	159		4	6	54	113	134
5	1	61	147	165		4	7	55	117	139
5	2	62	152	170		4	8	56	122	144
5	3	63	157	176		4	9	57	126	149
5	4	64	162	181		4	10	58	131	155
5	5	65	167	187		4	11	59	135	160
5	6	66	172	193						
5	7	67	177	199		5	0	60	140	165
5	8	68	183	205		5	1	61	144	171
5	9	69	188	211		5	2	62	149	177
5	10	70	194	217		5	3	63	154	182
5	11	71	199	223		5	4	64	159	188
						5	5	65	164	194
6	0	72	205	229		5	6	66	169	200
6	1	73	211	236		5	7	67	174	206
6	2	74	217	242		5	8	68	180	212
6	3	75	222	249		5	9	69	185	219
6	4	76	228	255		5	10	70	190	225
6	5	77	234	262		5	11	71	196	232
6	6	78	241	269						
6	7	79	247	276		6	0	72	201	238
6	8	80	253	283		6	1	73	207	245
6	9	81	259	290		6	2	74	213	252
6	10	82	266	297		6	3	75	218	258
	11	83	272	305		6	4	76	224	265
						6	5	77	230	272
7	0	84	279	312		6	6	78	236	280

When using BMI to determine overweight, use the following formula.
Overweight is defined as a Body Mass Index (BMI) > 27.8 for men and 27.3 for women, and Severely Overweight as a BMI>31.1 for men and 32.3 for women. BMI is calculated by W/H^2. Where H=Height in meters squared and W=Weight in kilograms.

BODY MASS INDEX FORMULA

If you are interested in how BMI is calculated, this page has the mathematical formulas. You can calculate BMI using either feet, inches, and pounds, or meters, centimeters, and kilograms.

ENGLISH FORMULA

Body Mass Index can be calculated using pounds and inches with this equation

$$BMI = \left(\frac{\text{Weight in Pounds}}{(\text{Height in inches}) \times (\text{Height in Inches})} \right) X\ 703$$

For example, a person who weighs 220 pounds and is 6 feet 3 inches tall has a BMI of 27.5.

$$\left(\frac{220 \text{ lbs.}}{(75 \text{ inches}) \times (75 \text{ inches})} \right) \times 703 = 27.5$$

METRIC FORMULA

Body Mass Index can also be calculated using kilograms and meters (or centimeters).

$$BMI = \frac{\text{Weight in Kilograms}}{(\text{Height in Meters}) \times (\text{Height in Meters})}$$

Or

$$BMI = \frac{\text{Weight in Kilograms}}{(\text{Height in centimeters}) \times (\text{Height in centimeters})} X\ 10{,}000$$

For example, a person who weighs 99.79 Kilograms and is 1.905 Meters (190.50 centimeters) tall has a BMI of 27.5.

$$BMI = \frac{99.79 \text{ Kg}}{(1.905 \text{ m}) \times (1.905 \text{ m})} = 27.5$$

FAINTING DURING SPIROMETRY

Fainting is the most common complication of spirometry. Although it rarely results in injury, it is disturbing to both subject and technician and may be hazardous in some instances. For safety of the subject, piece of mind of the technician or nurse, and for optimal test quality, it helps to understand fainting and how to prevent it.

The Forced Vital Capacity (FVC) maneuver, the basic maneuver performed during spirometry, requires an inhalation to total lung capacity following by a maximal blasting effort which is then sustained to blowout all of the subject's air as rapidly and completely as possible. This maneuver is best demonstrated with the flow volume curve. The initial blast produces the sharp peak at the beginning of the maneuver, continued effort causes expulsion of air at the maximal achievable flow rate. Sustained effort results in complete exhalation.

If you monitor the pressure in the chest during the FVC maneuver, you will find a very high intra-thoracic pressure during the earliest part of the maneuver. This may be sustained at a high level by some subjects. The effect of this increased intra-thoracic pressure is to form a large pressure gradient for blood which is returning to the heart through the veins. If the intra-thoracic pressure is high enough, it can markedly reduce venous return to the heart which results in a fall in cardiac output and blood pressure. The reduced blood pressure or cardiac output can cause a drop in blood supply to the brain and other organs. This drop in blood pressure, if large enough and sustained long enough, can cause a loss of consciousness or fainting.

Why doesn't this happen all of the time? Although it is necessary to develop a high intra-thoracic pressure to achieve peak flow, it is not necessary to maintain such a high pressure to maintain maximal flow during the latter phase of the expiratory effort. For most subjects, intra-thoracic pressure is high for only 1-3 seconds. After that, pressure falls to a low value during the latter part of the expiratory effort. In some subjects, particularly muscular subjects with airways obstruction (chronic bronchitis, emphysema, and asthma) the presence of airflow obstruction prevents the fall in intra-thoracic pressure. The more muscular subjects are capable of maintaining a high pressure for a prolonged period of time. These are the subjects who are prone to fainting.

How can you prevent fainting? Since a high intra-thoracic pressure is needed only for the first 1-3 seconds of the maneuver, it is possible to coach subjects to avoid lightheadedness or fainting. For subjects who have had previous experience with lightheadedness, or in whom you see evidence that they might faint, you can coach them to do a more relaxed expiratory effort during the latter phase of the forced vital capacity maneuver (e.g. "O.K. BLAST!" "Now keep blowing, keep blowing...o.k. now keep blowing but not so hard, keep blowing but not so hard...) With practice you can coach your subjects through this maneuver without sequential efforts to be sure that maximal flow has been reached (the flow volume curve, FVC and FEV1 should be very comparable).

In summary, fainting is due to high intra-thoracic pressure during the forced vital capacity maneuver. It occurs most commonly in muscular subjects with airflow obstruction. It can be avoided by cautiously observing your subject and coaching them to do a slightly less forceful, but still sustained, effort during the late portion of the forced vital capacity maneuver.

Courtesy, Dr Paul Scanlon, Director, Mayo Pulmonary Services.

WHY THREE TRIALS

Historically the ATS Spirometry Standard has been recommended by OSHA as the basis for providing NIOSH approved spirometry training. (See OSHA Standards and Compliance letter 3/5/90.) On page 326 of the ATS/ERS Standard, under the paragraph entitled "Test results selection", it states: Volume-Time or Flow-Volume curves from the **best three FVC maneuvers must be retained**. Further on Page 326 it states: "Spirometric variables should be measured from a series of **at least three acceptable forced expiratory curves"**.

A valid record, therefore, requires that there be a **minimum of 3 Acceptable curves** (acceptable means the absence of acceptability errors), of which the two best FVC and FEV1 meet the 150ml Repeatability criteria (see page 325 of the Standard). When this criterian is met, it gives confidence to the reader that the best effort was obtained, and the values measured represent the truth of lung function.

Although an invalid record can show a subject to be in the normal range, it could be a false negative, or if in the abnormal range, a false positive. When using spirometry data in a surveillance program where data is trended to determine if function is declining at an abnormal rate, even though the data may yet still be in the "normal" range, it is vital to get the absolute true values, which is represented by a valid test. Otherwise, the trends may be obscured.

To encourage testers to continue testing until valid data is obtained, the Standard states on page 326 under the paragraph entitled "Maximum number of maneuvers" that the test may be repeated up to a maximum of **eight times** in any one test session. It can be observed in the chart on page 76, that a subject's FVC & FEV_1 continue to get larger with each trial up to and including trial 5. There are two reasons for these phenomena.

1. As the number of trials increase, the lungs become more compliant, or stretched out, up to its normal anatomical limit. This is known as the **Compliance** curve.

2. The more the test is repeated the better the subject understands what is required, therefore values increase. This is called the **Learning** curve.

3. After the 5^{th} trial, the **fatigue (and subject hostility)** curve supersedes the learning and compliance curve so data values tend to go down.

If the distributions seen on the graph on page 76 where the highest spirometry values occur are added together it can be seen they fall on trials 3(17.4%) 4(19.7%) and 5(22%). Since the best three occur most frequently on trials 3, 4 and 5 (59% of the time), it argues that a standard test set of trials be set for five. The Spirometer report on page 78 shows an acceptable record that meets all repeatability requirements.

COMMUNICATION TIPS

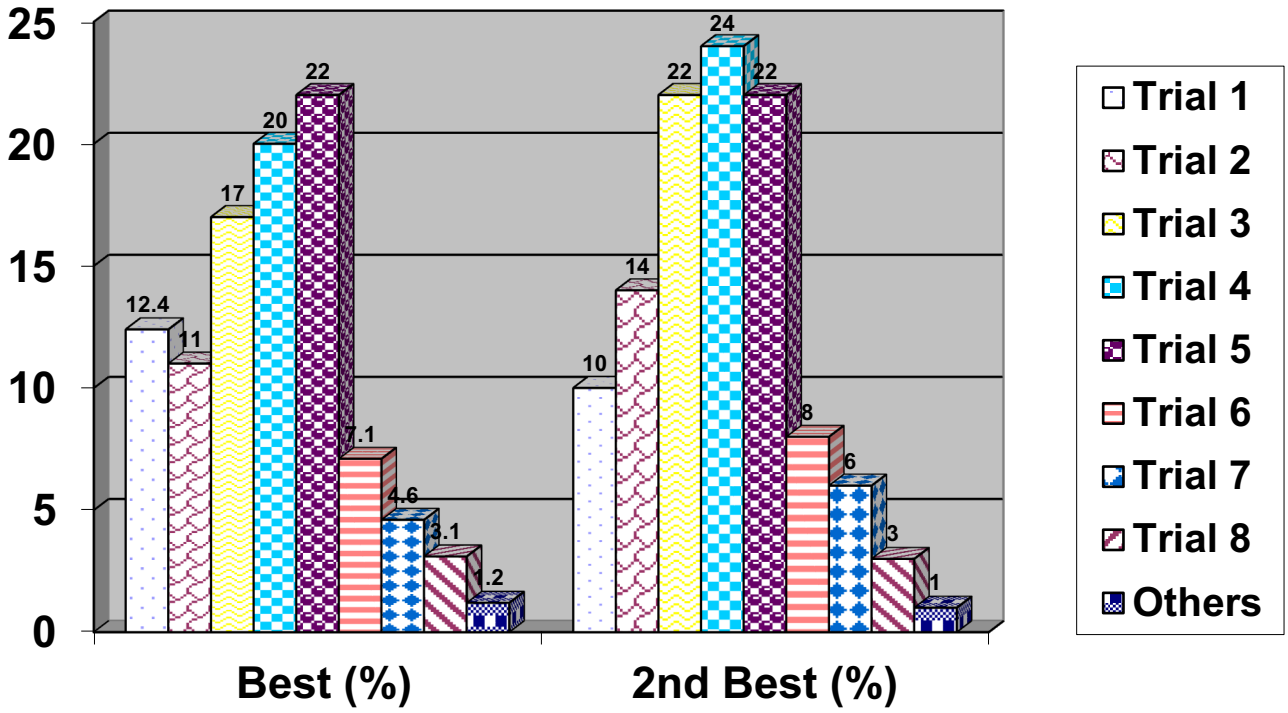
When presenting test instructions, keep in mind the following communication tips:

- 7% What you say
- 38% Tone of Voice
- 55% Body Language

From "Speaking Up" by Robert McGarvey

"Content and the facts play a very minor role in your impact, perhaps 7 percent," says management communications consultant Dr. Roger Flax. Certainly, that goes against the common grain, but Flax is backed by research. "Tone of voice accounts for 38 percent of your impact, while nonverbal elements such as dress, grooming and body language shape 55 percent," continues New Jersey-based Flax, citing the current findings on how and why messages seep into audiences. **"Add it up, and 93 percent of your impact had nothing to do with content."**

DISTRIBUTION OF BEST AND SECOND BEST TRIALS



BEST TRIAL N = 15000
SECOND BEST TRIAL N = 135677

CIRCADIAN VARIATION

Circadian is Latin for 'about a day'. It refers to a 24- hour cycle in the physiologic process that affects body temperature, hormone levels, heart rate and lung function. Generally, the FVC and FEV_1 increases in volume between 6am and 12pm, then decreases in the afternoon, evening and overnight. Given the phenomena is operative, longitudinal testing must take into account the time of day that testing is scheduled.

Below is a summary of a landmark paper describing the effect of time of day on the FEV_1 and the FVC.

Circadian variation of F.E.V. in shift workers (Brit J. Ind. Med, 1969, 26, 121-125)

E. Guberan, M.K. Williams, Joan Walford, and Margaret M. Smith
London School of Hygiene and Tropical Medicine T.U.C. Centenary Institute of Occupational Health, and the Medical Department, Electric Power Storage Co. Ltd., Dagenham Dock, Essex

The one-second forced expiratory volume (FEV_1) the forced vital capacity (FVC) and the oral temperature were measured in a group of men working a rotating three-shift system, 2 to 10 p.m. one week, 10 p.m. to 6 a.m. the next week and 6 a.m. until 2 p.m. the third week. The outside air temperature at the London Weather Centre was also obtained. Measurements were made on Mondays and Fridays at the beginning, middle, and end of the shift.

The mean FEV_1 of 19 normal men showed an increase of 0.15 liters (4.1%) between the beginning and end of both the morning shifts, a mean decrease of some 0.05 liter (1.5%) between the beginning and end of the afternoon shifts and little change during the night shifts. The circadian variation could not be attributed to industrial fume, smoking or a learning effect.

The findings will be of practical importance when FEV_1 is measured in shift workers to determine the effects of toxic substances on ventilatory capacity.
Brit J. Indust, Med., 1969, 26, 121-125

PULMONARY FUNCTION REPORT

Example

Patient Information

Name:	ID:	Birthdate: 4/13/1962
Height at test (in): 67.0	Sex: Male	Smoking history (pk-yrs):
Weight at test (lb): 164.0	Age at test: 41	Predicted set: Knudson 1976/1983

Comments:
Diagnosis:

Interpretation

NORMAL SPIROMETRIC VALUES indicate the absence of any significant degree of obstructive pulmonary impairment and/or restrictive ventilatory defect. This interpretation is valid only upon physician review and signature.

Site:
Physician:
Technician:

Effort protocol: ATS 1994

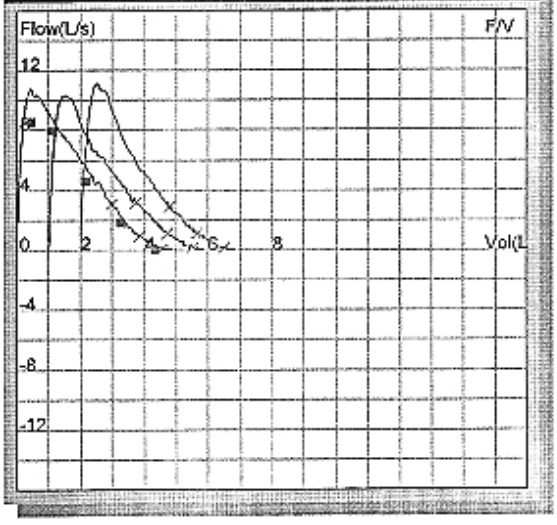
Test date/time: 06/18/03 08:00:51 AM
Number of efforts performed: 3

Results

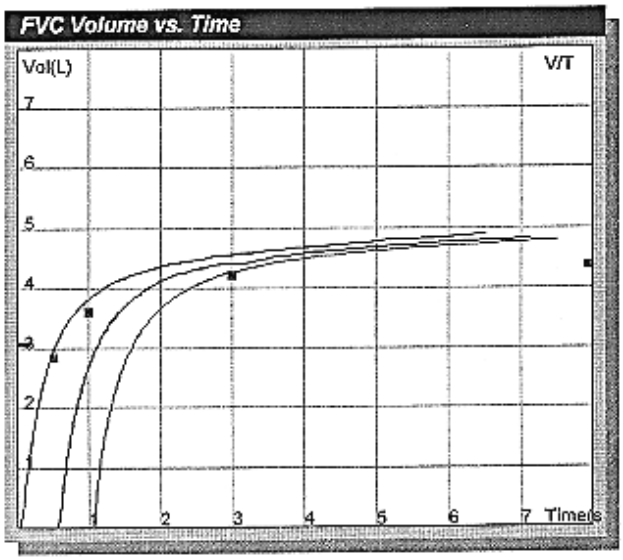
Result	Pred	Best	%Prd	Cons	%Prd	Cons	%Prd
FVC (L)	4.36	4.88	112%	4.83	111%	4.79	110%
FEV1 (L)	3.81	3.88	108%	3.79	105%	3.73	104%
FEV1/FVC	0.83	0.80	96%	0.78	94%	0.78	94%
FEF25-75% (L/s)	3.85	3.65	95%	3.30	86%	3.18	83%
PEFR (L/s)	8.57	10.83	126%	10.36	121%	11.18	130%
Vext %	---	1.99	—	1.77	—	2.22	—

Test comments:

FVC Flow vs. Volume



FVC Volume vs. Time

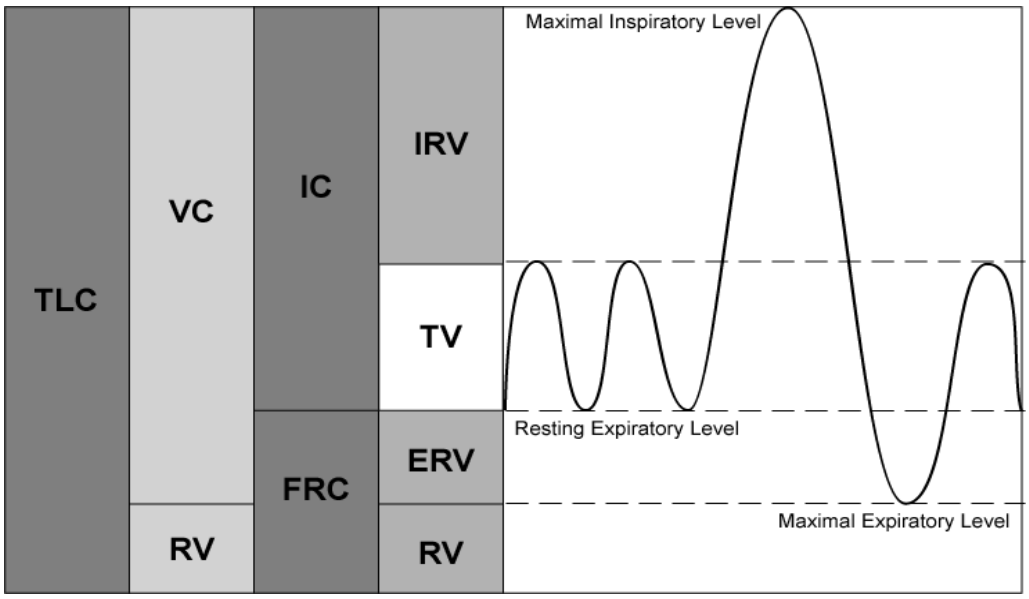


Chapter 6

LUNG ANATOMY

LUNG VOLUME NOMENCLATURE

The Lung volumes are anatomical measurements which can be measured by spirometric or other means. Since the volumes are static no time limit is imposed. The most important of these volumes is the VITAL CAPACITY (VC), which is the amount of air that can be expired following a maximal inspiration. The air that is left in the lung after a maximal expiration is called the RESIDUAL VOLUME (RV). At this level, closure of small airways prevents further expiration. If there is a significant loss of lung tissue, as seen in the condition called emphysema, where there are large 'holes' in the lung tissue, the Residual Volume is greatly increased at the expense of the Vital Capacity which becomes proportionately reduced. It will be evident that the measurement of Residual Volume cannot be done by simple spirometry. The Total Lung Capacity (TLC) is the sum of the VC & RV. This is an important measure when identifying Restrictive Lung Disease.



The above illustration shows the subdivisions of the lung volumes. The normal respiratory excursion or TIDAL VOLUME is that seen during quiet breathing.

TLC= Total Lung Capacity	IRV= Inspiratory Reserve Volume
VC= Vital Capacity	TV= Tidal Volume
RV= Residual Volume	ERV= Expiratory Reserve Volume
IC= Inspiratory Capacity	FRC= Functional Residual Capacity

LUNG ANATOMY AND PHYSIOLOGY

ANATOMY: AIRWAY STRUCTURE

The tracheobronchial tree constitutes a series of branching tubes whose function is to transport air into and out of the alveoli. These tubes can be classified into four groups:

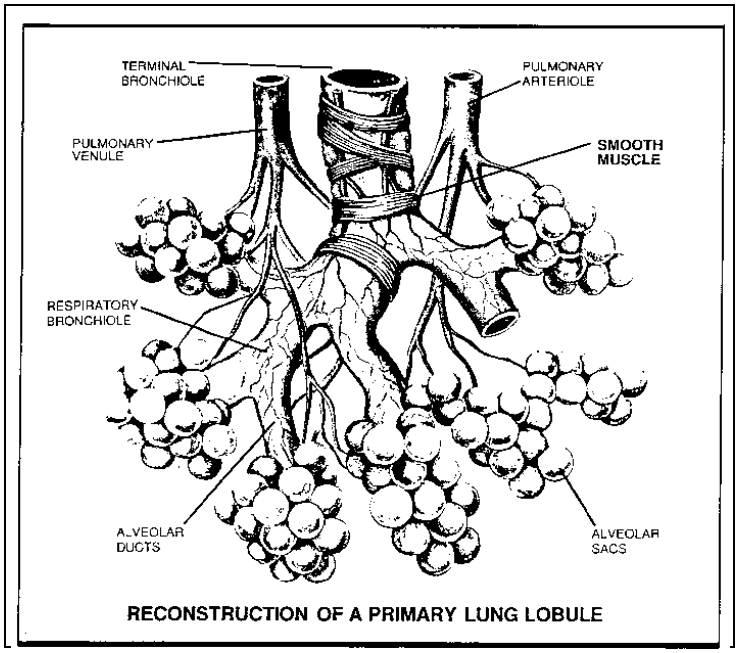
A. Upper airways - nasopharynx, oropharynx, and larynx.

B. Cartilaginous airways - trachea and bronchi.

C. Membranous airways - bronchioles.

D. Gas exchanges airways - respiratory bronchioles and alveolar ducts.

Upper Airways: Geometrically the upper air passages are complex and offer a large surface area to incoming air. The entire area is lined by ciliated columnar epithelium containing many mucous secreting glands. The mucous forms a continuous blanket on top of the cilia which beats in such a direction that the mucous layer is propelled toward the oropharynx where it is swallowed. Particulate matter entering with the air, if of sufficient mass, impinges on the mucous, becomes stuck, and is then swallowed. Aside from this cleansing property, the upper air passages warm or cool incoming air to body temperature and saturate it with water vapor.



RECONSTRUCTION OF A PRIMARY LUNG LOBULE

Anatomically the tracheobronchial tubes can be viewed as an inverted tree whose trunk is the trachea and where branches are the bronchi and bronchioles. The system of branching is, in general, **dichotomous, i.e., each parent branch gives rise to two daughter branches.** When the trachea is taken as generation zero, the bronchi branch some **23-26 times** before reaching the alveoli. In this system the **diameter (cross-sectional area) of the daughter branch is always smaller than the parent branch.** In other words, if one were to follow a single axial pathway from trachea to alveolus, the dimensions would progressively narrow. However, the number of bronchi and bronchioles in each successive branching rapidly increases and the total cross-sectional area of each branching also rapidly increases as one approaches the alveoli. Since resistance to air flow is inversely related to the cross-sectional area of the airways, one would expect the least resistance to be in the small airways (11th branch down to the 26th). Since they become more numerous than the larger airways (above the 11th branch to the mouth), their total cross-sectional area is greater. Resistance to airflow is, therefore, less in the small airways than in the larger airways.

The cartilaginous airways include the trachea and all its branching down to bronchi 1-3mm in diameter. The major supporters of these airways are incomplete cartilaginous rings, C shaped, and plates. Airways are lined with ciliated epithelial cells and mucous production goblet cells.

TERMINAL RESPIRATORY UNITS

Beyond the terminal bronchioles the airways contain the acinus (respiratory bronchioles, alveolar ducts and alveoli) in whose walls the pulmonary capillaries course and where gas exchange occurs. Gas exchange occurs across the alveolar-capillary membrane. The total alveolar surface of this membrane is roughly 70 square meters, or the size of a racquetball court, and the capillary blood volume in its walls is roughly 80-120cc.

PHYSIOLOGY: RESPIRATORY PRESSURES

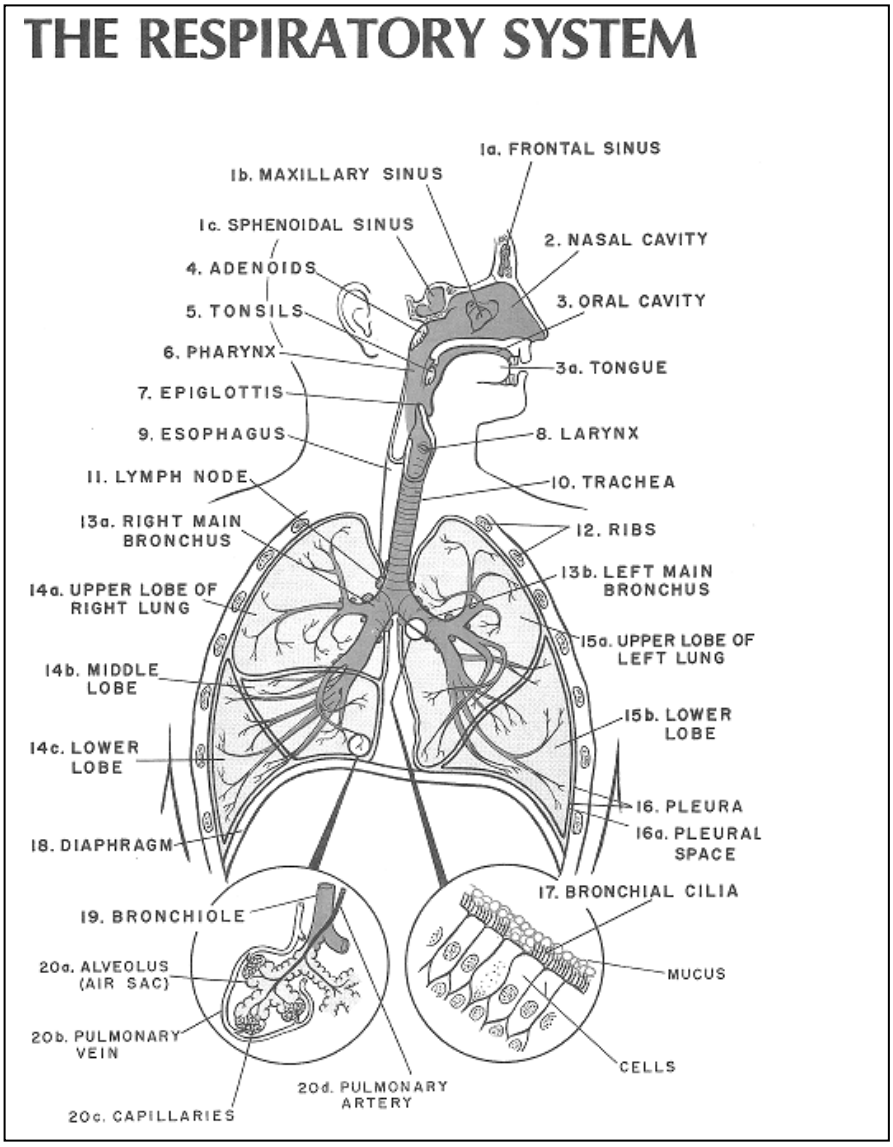
During inspiration a pressure difference is produced between mouth and alveoli by creating a sub atmospheric pressure in the pleural space. This is accomplished by active contraction of the intercostal muscles and the diaphragm - increasing thoracic volume, which is a closed space, this decreases the intra thoracic pressure, which is a closed space, and decreases. Thus, the pressure gradient is from mouth (atmospheric pressure) to alveoli (sub atmospheric pressure) producing a flow of air in the same direction, i.e., into the alveoli. Three points should be remembered here:

- Inspiration requires active muscular work
- Pleural pressure (intra thoracic pressure) is always sub atmospheric during inspiration
- The muscular work expended is due to stretching of the elastic lung and to the production of gas flow down through the airways.

DIAGRAM OF THE LUNGS

Normal, healthy lungs are compliant. **Compliance** is a term used to define the ability of the lungs to stretch and contract easily. At the peak of inspiration, the elastic lung tissue is stretched, like a rubber balloon. When the inspiratory muscles relax, the **elastic recoil** of the stretched lungs causes a positive pressure gradient from alveoli to mouth and expiration occurs. Normally expiration is a passive process. Emphysema, a destructive process, causes the elastic recoil of the lung to be diminished. Thus, to produce an adequate force for expiratory flow, the muscles of expiration, the diaphragm and intercostals, must be actively contracted.

Another term pertaining to **normal lung function** is "resistance". **Resistance** is a term used in reference to air flow in the airways, similar to "friction loss" in water flow in a pipe.



LUNG DEFENSE MECHANISMS: SUMMARY

1. Large particles (>10M micrometers) are caught by the hair in the nose and mucous in the upper airways.

2. Coughing: a high shearing force or burst of air that ejects particles in medium and large airways.

3. The **muco-ciliary escalator consists of 3 parts**: **goblet cells**, **cilia**, and the **mucous blanket**. Goblet cells secrete mucous that rises and floats on the microscopic cilia. The cilia are microscopic hair-like structures that line all of your airways that move in a waving motion moving the mucous in an upward direction from alveoli to mouth.

4. Alveolar macrophages are large white blood cells which ingest small particles.

5. Immune system: Tries to destroy foreign organic material, molds etc….

Gasps and Sighs

- **Spread flat, the two pounds of alveoli in the lungs would cover the floor of a racquetball court – about 50 times more space that the skin would occupy.**
- **Resting lungs expand 12 or 17 times per minute, accepting half a quart of air with each inhalation. During strenuous exercise, the lungs may expand up to 42 times per minute, taking in as much as five quarts of air each time.**
- **The rush of air produced by a cough moves as fast as 600 miles per hour; a sneeze can be even more propulsive.**
- **Each second, the body makes 500 trillion copies of hemoglobin molecules and distributes them among 25 trillion red blood cells.**
- **A single alveolus fills and empties more than 15,000 times in a single day of normal breathing.**
- **Abnormal contractions of the diaphragm cause hiccups.**

Chapter 7

LUNG PATTERNS

CATEGORIES OF LUNG DISEASE

Lung diseases fall into two distinct categories; **Obstructive** and **Restrictive** impairments. Obstructive diseases are related to air flow abnormalities; Restrictive diseases tend to limit the volume capabilities of the lung, i.e. the ability to inhale adequate quantities of air.

Obstructive disease, which is caused primarily from smoking, environmental pollution and occupational exposures, occurs ten times as frequently as restrictive conditions. Many respiratory diseases show characteristics of both. Causes of diseases can also be categorized. Conditions such as bronchitis, bronchiectasis and pneumonia are usually the result of an infection caused by a variety of factors. The general category of restrictive diseases called pneumoconiosis occurs from inhalation of tiny dust particles that remain in the lungs.

Spirometry Categorizes lung function into one of 4 conditions:

NORMAL

OBSTRUCTIVE

RESTRICTIVE

MIXED OBSTRUCTIVE/ RESTRICTIVE

85% - 90% of abnormalities are Obstructive in nature.
(Bronchitis, Emphysema, Asthma)
10%-15% of abnormalities are Restrictive in nature.
(Pneumoconiosis, Silicosis, Asbestosis, etc)

Spirometry allows us to make an Interpretation, NOT a DIAGNOSIS

CATEGORIES: CAUSE AND EFFECT

OBSTRUCTIVE

Causes

- Airway inflammation and mucus production (bronchitis)
- Airway hyper reactivity (asthma)
- Loss of airway support and alveolar destruction (emphysema)

Effects

- Reduced airflow during exhalation
- Cough, phlegm, wheezing
- Shortness of breath
- Large lungs on chest x-ray (hyperinflation due to trapped air)

Examples of exposure induced diseases

- Industrial bronchitis from SO_2 exposures (oil refinery workers, smelter workers, paper makers, wine makers, diesel engine operators)
- Occupational asthma from exposures to isocyanates such as TDI, grain, and cereal workers, joiners, sawmill operators, western red cedar and wood workers (15%)
- Byssinosis from cotton dust (textile industry, cotton ginning) (10%)
- Acute irritant exposures (detergent enzyme workers & printers)
- Emphysema from Cadmium fumes in welding and galvanizing

RESTRICTIVE

Causes

- Excessive particle load
- Ineffective particle clearance
- Inflammatory response caused by macrophages
- Obesity
- Chest wall deformities
- Neuro-Muscular Disorders (Myasthenia Gravis)

Effects

- Reduced lung volume
- Decreased oxygen uptake
- Opacities on chest x-ray
- Shortness of breath

Examples of exposure induced diseases

- Coal worker's pneumoconiosis (7.3% of 150,000 coal miners)
- Silicosis (3% of 1,600,000 hard rock miners and sand blasters)
- Asbestosis (20% of 760,000) (demolition, shipyard workers
- Hypersensitivity pneumonitis (8-10% of workforce) (sugar cane workers-baggassosis, cork manufacturers-suberosis, farmers lung-mouldy hay)
- Siderosis (from iron oxides or Metabolic iron exposures) (arc welders and cutters)

OCCUPATIONAL LUNG DISEASES

The lung is both a target and a portal of entry for toxic substances. The likelihood of toxic exposure is high; for example, an estimated 1.6 million workers each year are potentially exposed to silica dust alone. The recognition of occupational lung diseases may be difficult since the latent period for such diseases may be as long as 15 years for silicosis and 30 years or more for asbestos-related diseases. Other factors, such as cigarette smoking, may also contribute significantly to the disease process and hence obscure the association between work and the disease.

Six important components of occupational lung diseases are described below. Each is preventable, although years of effective control measures will be required to eliminate diseases of long latency. Because of the rapid rate at which new potentially toxic agents are introduced, surveillance will be essential if epidemics of occupational lung diseases are to be avoided. These diseases, as well as lung cancer and occupational asthma, are briefly discussed below.

A. RESTRICTIVE DISEASES

Pneumoconiosis: The pneumoconiosis are some of the best known of the occupational lung diseases, yet for a long time the courts doubted their existence and refused to consider them as compensable illnesses. Most causes of pneumoconiosis are inorganic dusts or fibers, with particles less than 5 microns in size. Particles of this size are called "respirable particulates." Since these particulates are invisible, it is possible to be exposed without knowing it. However, many of the heaviest exposures were accompanied by larger particulates so that the industries were recognizably "dusty".

Asbestosis: Asbestosis is characterized by diffuse, extensive scarring of the interstitial lung tissue (fibrosis) and progressive shortness of breath. Once established, the disease progresses even after exposure ends; there is no specific treatment. The latency period is 10-20 years. Smoking appears to increase the risk of death from asbestosis by a factor of two to three and lung cancer by 90 times. Longitudinal studies of groups of asbestos insulation workers and shipyard workers have revealed that 10%-18% may be expected to die of asbestosis.

Silicosis: (White Lung) Although the ill effects of exposure to free crystalline silica have been known for centuries, the prevalence of disabling silicosis remains high in certain groups of workers. Nearly 60,000 currently exposed workers in mines and foundries, in abrasive blasting operations, and in stone, clay, and glass manufacturing may be expected to suffer some degree of silicosis. Fibrosis is around the bronchi (peri-bronchial).

Coal workers pneumoconiosis (CWP): (Black Lung) The estimated prevalence of CWP among currently employed coal miners is about 4.5%. Approximately 0.2 % of coal workers have been diagnosed as having progressive massive fibrosis, a potentially disabling form of CWP. In 1974, there were an estimated 19,400 cases of CWP. Some 4,000 deaths each year are attributed to legislatively defined "black lung disease".

Hypersensitivity Pneumonitis: Hypersensitivity Pneumonitis is also referred to as Extrinsic Allergic Alveolitis. This disease occurs mainly in the alveoli and terminal bronchi in response to organic dusts associated with specific occupations. In some cases, they are animal proteins (such as bird breeder's lung and furrier's lung), vegetable proteins (such as coffee worker's lung) or fungi. The workers develop an acute illness with cough and shortness of breath, usually without wheezing, but often accompanied by chills and fever. The first occurrence may be mistaken for a "flu syndrome". Once workers are sensitized, they may respond to very small doses of the allergen. Fluid accumulates in the alveoli interfering with the oxygen diffusing capacity. Termination of exposure allows the acute phase to resolve over a period of 1-2 weeks. However, recurrent exposures may produce a chronic disease with interstitial fibrosis and severe shortness of breath.

Granulomatous Disease: Granulomas are inflammatory responses that occur as a reaction to infections (e.g., tuberculosis) or toxins. Large inflammatory cells move in and begin to collect around the point of exposure. Later fibrous tissue migrates in and around the site, producing a globular mass that can be seen under the microscope. Berylliosis is the best know occupational example of this class of lung diseases.

Other Health Conditions: Several preexisting conditions can cause restrictive patterns. These include pregnancy, obesity, anatomical abnormalities, and thoracic or abdominal surgery. Although these conditions are not occupationally induced, they are mentioned here because their impact must be considered when reviewing spirometric results.

Lung cancer: The single most important cause of lung cancer is tobacco smoke. However, numerous occupational agents are associated with lung cancer, including arsenic, asbestos, chloroethers, chromates, ionizing radiation, nickel, and polynuclear aromatic hydrocarbon compounds. Tobacco smoke may interact synergistically with some of these agents (e.g., asbestos) to sharply increase the risk. Of special concern in this regard are workers currently or previously exposed to asbestos (estimated from 7.6 to 13.2 million); as many as 6,000 asbestos-related lung cancers may occur annually.

B. OBSTRUCTIVE DISEASES

Occupational asthma: Hypersensitivity reactions to a wide variety of occupational organic and inorganic agents can cause asthma and hypersensitivity pneumonitis. The prevalence of occupational asthma varies from 10% to nearly 100% of workers in certain occupations. Many agents are incriminated as etiologic for occupational asthma, including grain dusts, flour, metals, inorganic chemicals, isocyanates, enzymes, and fungi. On subsequent exposures, the smooth muscles of the bronchial tubes go into a spasm and some of the smaller airways close down. Excessive mucous is also produced, which further aggravates the problem by clogging small airways. Coughing, difficulty breathing, and wheezing are common symptoms. The list of agents associated with hypersensitivity pneumonitis is also long. If exposure continues, these conditions may result in progressive, irreversible pulmonary fibrosis.

Reactive Airways Dysfunction Syndrome (RADS): Reactive Airways Dysfunction Syndrome mimics asthma but is due to an irritant rather than an allergic stimulus. Individuals with RADS will experience airflow obstruction at exposure levels much lower than would produce a response in non-affected individuals. One special case of RADS involves a

heightened response to cold air. It is known that asthmatics can have their attacks initiated by cold air. Other individuals with no known history of asthma may develop broncho-constriction or tightness and shortness of breath when exposed to cold air, either on the job or during exercise. Removal from the exposure usually causes symptoms to subside within 1-2 hours.

Emphysema: An anatomic alteration of the lung characterized by an abnormal enlargement of the air spaces distal to the terminal, non-respiratory bronchiole, accompanied by destructive changes of the alveolar wall. Most of them are associated with cigarette smoking, however, it can also be chemically induced (e.g. cadmium). When pressure in the chest begins to increase upon exhalation, these bronchi may collapse, trapping air inside. As a result, the air sacs remain partially expanded. Shortness of breath is a permanent problem and trying to breath faster and more deeply only causes more air to become trapped inside. The lungs frequently become distended, causing a barrel-chested appearance. The disease is progressive and damage to the heart is a frequent side effect.

Chronic bronchitis: A clinical disorder characterized by excessive mucus secretion in the bronchial tree. It is manifested by chronic or recurrent productive cough on most days for a minimum of three months of the year, and for not less than two successive years. Also associated with smoking but can be induced by such chemicals as acrolein or SO_2. Inflammation, swelling, and increased mucous production occur, fostering chronic bacterial infections in the mucous-plugged small airways. Symptoms include shortness of breath and a persistent and productive cough.

Byssinosis: (Brown Lung) This condition, characterized by both acute (reversible) and chronic lung disease, is associated with inhalation of the dusts of cotton, flax, or hemp. Symptoms include "chest tightness," cough, and obstruction of the small airways. Severely impaired lung function has disabled an estimated 35,000 current and retired textile workers. The specific causal agent(s) in the various dusts are yet to be identified.

C. PULMONARY DISEASES THAT SHOW EITHER OBSTRUCTIVE OR RESTRICTIVE PATTERNS

Pneumonias: Pneumonias may have a restrictive effect due to accumulation of fluid and inflammatory cells in the alveoli (much like alveolitis) or an obstructive effect due to accumulation of cells around the bronchi (bronchial pneumonia). Pneumonias can arise as part of a toxic process, or more commonly, through infections. Occupational lung disease of infectious origin occurs primarily in health care workers, childcare workers, and animal care workers. The offending agents may be fungi, bacteria, viruses, or other microorganisms. In many cases these diseases are accompanied by chills and fever.

Pneumoconiosis: Although pneumoconiosis are primarily restrictive diseases, in advanced cases the fibrous tissue may impinge on the bronchial tree causing obstructive symptoms as well.

ASBESTOS RELATED DISEASES

RESTRICTION

Pulmonary Fibrosis

- Asbestosis

Pleural disease

- Pleural plaques
- Pleural thickening
- Pleural effusion

LUNG CANCER

Neoplastic conditions

- Cancer of lung
- Cancer of larynx
- Cancer of GI tract
- Mesothelioma
  - Pleural
  - Peritoneal

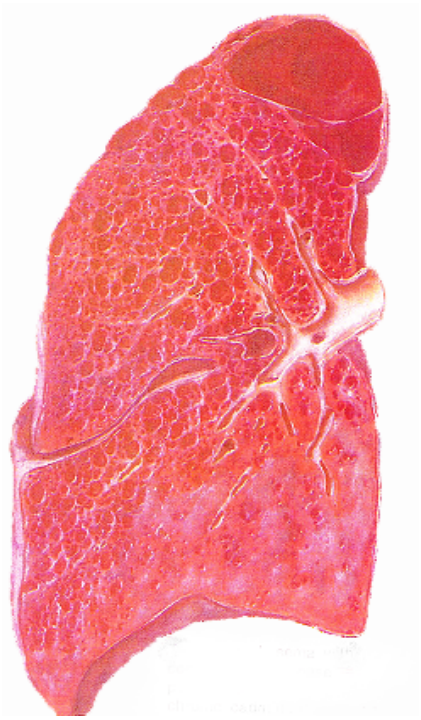
Causes

- Cigarette smoking
- Asbestos
- Uranium, coal tars, chromium, nickel, arsenic

Effects

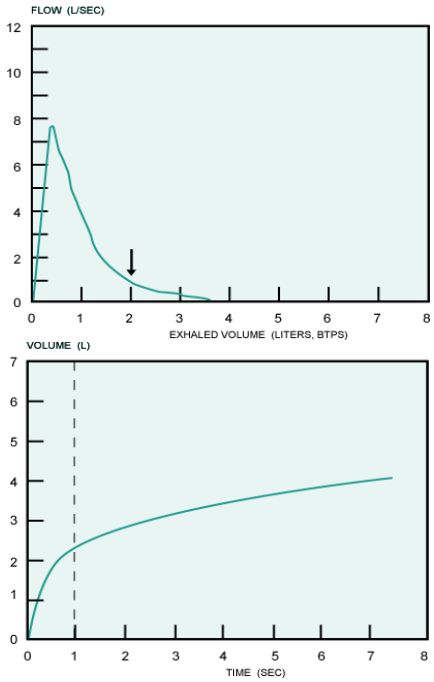
- Abnormal cells in sputum
- Opacity on chest x-ray
- 95 % fatality within 5 years.

EMPHYSEMA



This Obstructive Lung disease results in Spirograms that are similar to the following examples below.

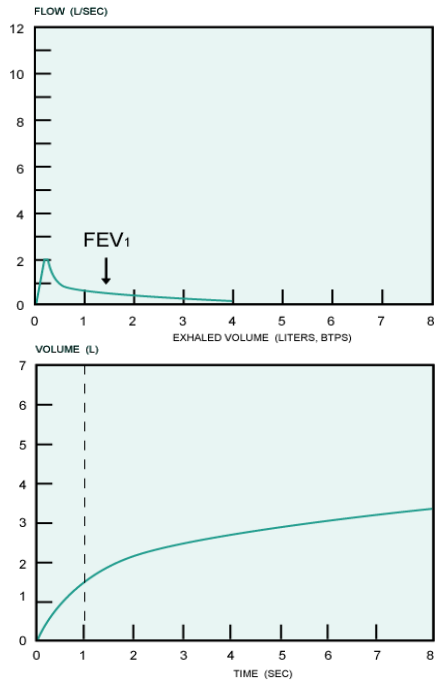
MODERATE AIRWAYS OBSTRUCTION



Flow - Volume

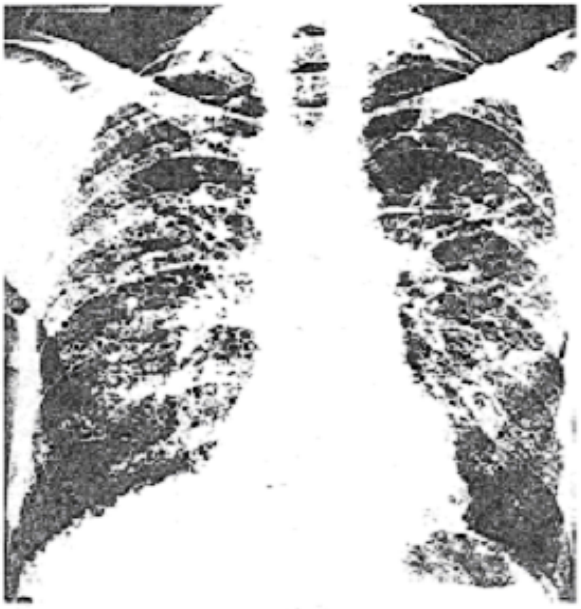
Volume - Time

SEVERE AIRWAYS OBSTRUCTION

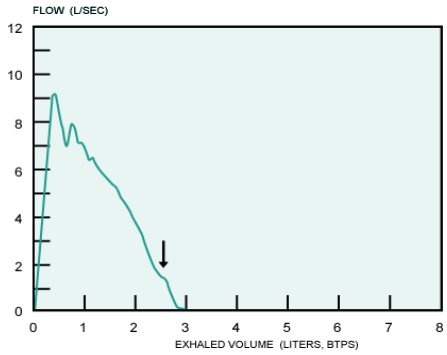


ASBESTOSIS

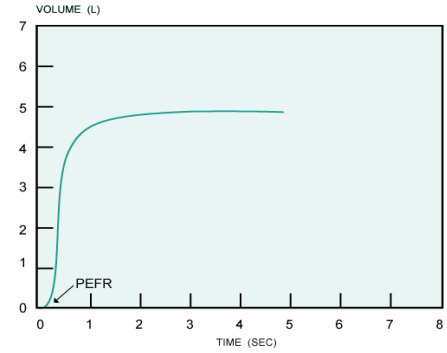
Advanced asbestosis – This Restrictive lung disease results in Spirogram that are similar to the following examples



MODERATE AIRWAYS RESTRICTION

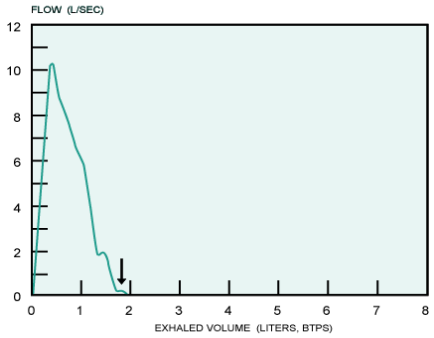


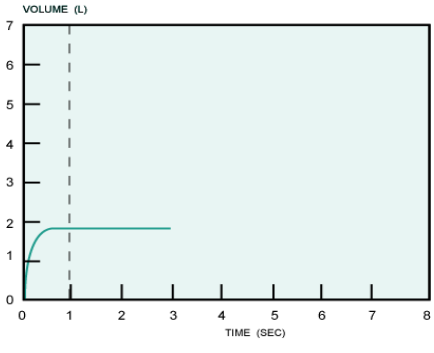
Flow-Volume



Volume-Time

SEVERE AIRWAYS RESTRICTION





COMMON QUESTIONS ABOUT OBSTRUCTION

Q. What is airway obstruction?

A. Obstruction means that you can't blow air out of your lungs as fast as you should.

Q. What causes airway obstruction?

A. If you are over age 40 and have smoked cigarettes, the most likely cause is bronchitis and emphysema of the lungs due to smoking. If you are a young non-smoker, the most likely cause is asthma.

Q. Could it be caused by my job?

A. Long term exposure to dusts, smoke or fumes may cause airway obstruction in some workers. Smoking, asthma and other non- occupational exposures and diseases may contribute to the development of airway obstruction. Separation of these effects requires further medical evaluation.

Q. Why don't I have any symptoms?

A. Borderline and mild degrees of obstruction usually do not cause symptoms because the lungs have twice the function you usually need. Moderate to severe obstruction, however, causes shortness of breath with exertion or even at rest.

Q. What can I do to keep it from getting worse?

A. Quit smoking. You are one of the minorities of persons whose lungs are susceptible to cigarette smoke. If you keep smoking, your lung function will get worse. If you decide to quit, your lung function will return to normal and slow the rate of decline due to aging.

If you are working in an environment where you may inhale dusts, fumes, or chemicals, talk with your supervisor about methods of decreasing your risk of exposures.

Q. Are there any drugs which might help?

A. If you become short of breath or wheeze due to obstruction, your doctor may prescribe bronchodilator drugs. These drugs are especially helpful if asthma is the cause.

COMMON QUESTIONS ABOUT RESTRICTION

Q. What is lung restriction?

A. Restriction means that you could not fill your lungs with as much air as you should.

Q. What causes restriction?

A. Mild restriction is often caused by being overweight. Fat prevents the chest from expanding fully. Perhaps you merely did not try hard enough to take as deep a breath as possible or did not empty your lungs completely during the test. A curvature of the spine or pneumonia are other causes.

Q. Could it be caused by my job?

A. Years of exposure to a dusty work environment without protection can cause scarring of the lungs and restriction. A chest x-ray will show this scarring or "fibrosis" as white patches.

Q. What should I do to find the cause?

A. Repeat the lung function test or get a chest x-ray if you have not had one in the last year. Discuss the results with your doctor.

Q. What can I do to keep it from getting worse?

A. If you are working in an environment where you may inhale dusts, fumes, or chemicals, talk with your supervisor about methods of decreasing your risk of exposures.

Chapter 8

MANUAL CALCULATION OF TEST RESULTS

CALCULATION OUTLINE

1. Measure FVC in each tracing from baseline to plateau. Subtract baseline if other than zero.

2. Select largest FVC from the three acceptable tracings. Record on data sheet.

3. Measure FEV_1 in each curve.

4. Select largest FEV_1 from the three tracings. (Usually found on the same curve as the largest FVC). Record on data sheet.

5. Determine BTPS correction factor from table using ambient temperature.

6. Multiply (OBS=Observed) values by BTPS correction factor to obtain BTPS corrected values and likewise for the FEV_1.

7. For $FEV_1/FVC\%$, divide:

   $FEV_{1(OBS)}$ by the $FVC_{(OBS)} = FEV_1/FVC\%_{(OBS)}$, then multiply by 100 to convert to a percentage

   (Note: No BTPS Correction Required)

8. Determine predicted normals of the FVC, FEV_1 and $FEV_1/FVC\%$ from the NHANES lll Reference Value Chart equations or look-up tables using sex, height and age. In non-Caucasians, FEV_1 predicted and FVC predicted must be multiplied 0.88 ethnic correction factor.

9. Determine % of predicted as shown:

   FVC_{OBS} / FVC_{PRED} = FVC% predicted normal

   $FEV_{1\ OBS}/FEV_{1\ PRED}$ = FEV_1 % predicted normal

   $FEV_1/FVC\%_{OBS}$ divided by $FEV_1/FVC\%_{PRED}$ = $FEV_1/FVC\%$ predicted normal

10. Summary:

    $FVC_{\ ATPS}$ x BTPS correction factor = $FVC_{OBS\ (BTPS)}$

    $FEV_{1\ ATPS}$ x BTPS correction factor = $FEV_{1\ OBS\ (BTPS)}$

    $FEV_{1\ OBS}/FVC_{OBS}$ x 100 = $FEV_1/FVC\%_{OBS(BTPS)}$

    FVC_{OBS}/FVC_{PRED} = FVC% predicted normal

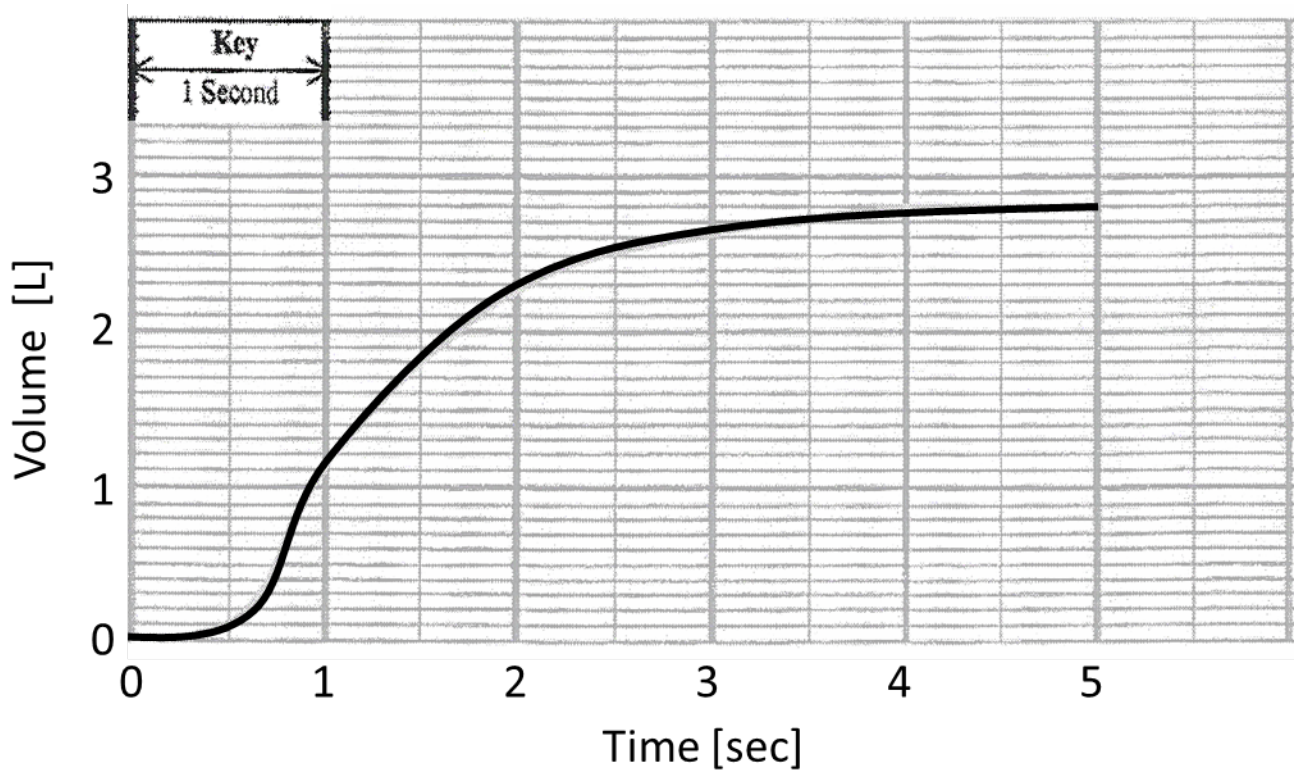
    $FEV_{1\ OBS}/FEV_{1\ PRED}$ = FEV_1 % predicted normal

    $FEV_1/FVC\%_{OBS}$ divided by $FEV_1/FVC\%_{PRED}$ = $FEV_1/FVC\%$ predicted normal

Note: If measures of flow rate are made i.e. $FEV_{25-75\%}$, values must be corrected to BTPS.

MANUAL CALCULATION EXERCISE

Example: **Forty yr. old female with "mild" asthma. She is Caucasian, height 62", ambient temp. 25°C, and we are testing under 3000 feet.**



Work Table

PARAMETER	ATPS	BTPS Correction Factor	BTPS True Value	VALUE		RACE ADJUSTED VALUE	%PRED.
				PREDICTED	LLN		
FEV_1 L		X =		÷			= %
FVC L		X =		÷			= %
FEV_1/FVC %			%	÷ %	%	%	%

ATPH – Ambient Temperature Pressure Humidity
BTPS – Body Temperature Pressure Saturation with Water Vapor

DETERMINING THE ATPS VALUES FOR FEV_1

In this exercise, you determine the ATPH values for FEV_1.

1. Use the Volume-Time spirogram provided on page 93 to determine the FEV_1. This requires you to perform a back extrapolation to determine the "new" zero-time. (see below)
2. Draw a line tangent to the steepest part of the curve crossing the baseline.
3. From the new zero time, measure the 1-second distance on the baseline. (Use the time key to determine 1 second.)
4. Draw a line perpendicular (vertically) from the 1-second baseline point to the curve and establish the volume.
5. Record this amount in the ATPH column in the FEV_1 row on the chart located on page 93.

DETERMINING THE ATPS VALUES FOR FVC

In this exercise, you measure the FVC.

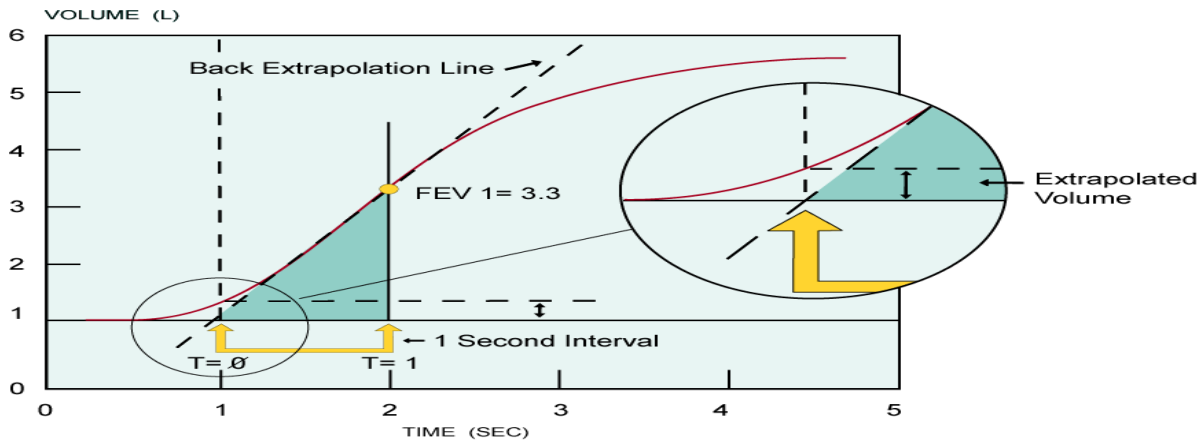
1. Measure the volume (vertical axis) from the baseline to the curve's plateau.
2. Record this amount in the ATPH column in the FVC row on page 93.

CALCULATING THE FEV1%

In this exercise you calculate the FEV_1 /FVC%. (FEV_1%)

1. Divide the FEV_1 by the FVC and express the result as a percentage.
(To calculate a percentage on most calculators, you can press the % button instead of multiplying by 100.)
3. Record this amount in the BTPS column in the FEV_1% row.

Back Extrapolation Example:



This quality control measurement determines if the FEV_1 is valid. If the check reveals a Back Extrapolation error to be present, then a spirometry quality flag is shown to instruct the subject to "START FASTER" or "SLOW START detected. **The criteria triggering this message is an EV of > 5% or 100ml whichever is greater.** The result of this type of error is a falsely high FEV_1 due to the movement of T_0 to the right.

USING THE BTPS CF TABLE

In this exercise, use the BTPS cf table.

1. Before testing, compare the spirometers temperature reading with an independent thermometer in the same vicinity as the spirometer. If there is a discrepancy, correct the spirometer temperature.

2. Look up the BTPS correction factor (cf).

Record this amount in the BTPS cf column in the FEV_1 row and in the FVC row on the chart on page 93.

Table1: Testing Below 3000 ft.

Temp C	Temp F	BTPS Factor
17	62.6	1.118
18	64.4	1.114
19	66.2	1.111
20	68.0	1.102
21	69.8	1.096
22	71.6	1.091
23	73.4	1.085
24	75.2	1.080
25	77.0	1.075
26	78.8	1.068
27	80.6	1.063
28	82.4	1.057
29	84.2	1.051
30	86.0	1.045
31	87.8	1.039
32	89.6	1.032
33	91.4	1.026
34	93.2	1.020
35	95.0	1.014
36	96.8	1.007
37	98.6	1.000
38	100.4	0.994
39	102.2	0.987
40	104.0	0.980

Table 2: Testing Above 3000 ft.

Temp C	Temp F	High Altitude BTPS Factor
20	68	**1.111**
21	70	**1.105**
22	71.5	**1.099**
23	73.5	**1.094**
24	75	**1.088**
25	77	**1.081**
26	79	**1.076**
27	80.5	**1.069**
28	82.5	**1.063**
29	84	**1.056**
30	86	**1.049**

CALCULATE THE BTPS CORRECTED VOLUMES

In this exercise, calculate the BTPS corrected FVC and FEV_1 values.

1. Multiply the ATPH volumes by the BTPS correction factor to obtain the BTPS corrected values for the FVC and FEV_1.
2. Enter data on chart located on page 93.

APPLYING RACE CORRECTION TO PREDICTED VALUE (IF REQUIRED)

OSHA, ACOEM and Knudson Recommend using the NHANES 111 Predicted equations

- 1.00 White, Italian, Hispanic, Black, African, Jamaican
- 0.88 - Cambodian, Chinese, Japanese, Korean, Laotian, Filipino, Vietnamese, East Indian, Pakistani
- 1.00 - Other: Eskimo, Hawaiian, American Indian, Iranian, Jordanian, Polynesian, Saudi Arabian, South American, Spanish, Indian

While the Global Lung Function Initiative (GLI)reference values are recommended as the default set for spirometry systems, facilities conducting spirometry may choose to use different reference value set that are deemed more appropriate for their population or for longitudinal studies. Therefore, for occupational spirometry testing in the USA, choosing to use the NHANES111 spirometry reference values is in full compliance with the 2019 Update of the ATS/ERS Spirometry Standards.

CALCULATING THE PERCENTAGE OF THE PREDICTED VALUE

In this exercise, you calculate the percentage of the predicted value. Use the data from the previous charts to complete the table. Multiply to ATPH values by the BTPS cf to obtain BTPS corrected values.

Divide the BTPS values by the predicted value and convert to a percent by multiplying by 100.

If race correction is required, multiply the predicted value by 0.88, then use this corrected prediction value to divide into the measured value, then, convert to percent. Record all answers in appropriate column of worktable.

Chapter 9

SPIROGRAM INTERPRETATIONS-PATTERN RECOGNITION

INTERPRETING RESULTS USING *PERCENTILES* TO DETERMINE THE LOWER LIMIT OF NORMAL

The practice of classifying spirometry values as abnormal if they fall below 80% of predicted for FVC and FEV_1 has no statistical basis in adult, or 70% of predicted for the FEV_1/FVC ratio. **The preferred method of ATS/ERS, ACOEM, and NIOSH, is to make judgments on abnormality by using the fifth percentile method to determine the LLN, as opposed to using the flat 80% cut offs** for FVC and FEV_1 measurements. This method identifies the point on the distribution curve below which 5% of asymptomatic normals are expected to fall and classified as abnormal. As age increases, pulmonary function declines, so does the fifth percentile LLN. This results in only 5% of normal subjects (those falling below the 5^{th} percentile) being falsely classified as abnormal. In contrast by using the 80% method, it results in increasing numbers of healthy subjects falling below the 80% cut offs as age increase, thereby creating a large pool of false positives in an aging population.

The LLN can be calculated using the following information: 1.645 (the lower 5% expressed as Standard Deviation units) times SEE (a measure of variability) minus the predicted value. The SEE comes from the prediction equation being used.

1.645 X SEE – Predicted Value = LLN (Lower Limit of Normal)

For example: using the 1983 Knudson prediction equations the 5^{th} percentile LLN for the FVC for a 40 year old man is 73.4% of predicted. This is significantly below the 80% of predicted cutoff. (Mary Townsend)

Although this interpretation is recommended, unfortunately this scheme is not widely used in existing spirometers. If it is desired to use the 5^{th} percentile method to determine the LLN go to the internet and "Google" **REFERENCE VALUE CALCULATOR**

1. Click on CDC-SPIROMETRY-TRAINING PROGRAM REFERENCE VALUE CALCULATOR. (bookmark it once you bring it up).
2. Select Reference Source to "Hankinson 1999" (this is NHANES III). Or to whatever prediction values you are using
3. Enter subject demographics.
4. Enter observed FVC, FEV_1, FEV1/FVC% and the FEF 25%- 75% from the **best acceptable trial**
5. Click on CALCULATE VALUES.
6. Compare LLN values calculated for each measurement then note the Percent of Predicted. (This is percent Obs/LLN.).

If you calculate the LLN percent and divide the LLN by the Predicted, you will note the percent gets lower as the subject ages.

As one gets old and shorter, one has a harder time meeting 80% of normal.

COMPARING OBSERVED TO PREDICTED NORMAL VALUES

A. Defining "Normal"

To interpret spirometric results, they must be compared either to a subject's previous results or to a published set of "predicted normal values.'" For any given population, there is an average value. Most people in the population will be close to this average, but some normal people will be above and others below the average. Individuals whose test results are far below the average may have an abnormality. If a subject's FVC or FEV_1 are less than 80% of the predicted value, the results are usually considered to be abnormal though using the 5th % is a fairer way to gauge one's abnormality.

Predicted average of normal values have been obtained by researchers who studied large populations in various environmental conditions using a variety of spirometric equipment. Because the conditions differed between studies, the predicted values differ. Below is a brief overview of some of the normal predicted values that are commonly used.

KORY (1961) These data were derived from the Veteran's Administration-Army Cooperative Study of Pulmonary Function. The Kory technique was used to determine zero time rather than the ATS preferred back extrapolation method. The study contained a large population of smokers and as a result the values generally are lower than those from other studies.

MORRIS (1971) These values were published in a 1971 issue of American Review of Respiratory Disease. They were derived from a population of healthy, non-smoking men and women living in a rural area with relatively little exposure to air pollution. The Kory Technique was used to determine zero time rather than the ATS-preferred back extrapolation method.

CHERNIACK (1972) This study used an automated wedge spirometer (similar to a bellows type spirometer). Study participants were lifetime nonsmokers who lived at sea level in a rural area. Zero time was calculated using the minimal flow threshold technique rather than the ATS-recommended back extrapolation method.

KNUDSON (1976) These values were published in a 1976 issue of American Review of Respiratory Disease. They were derived from an urban population of white individuals who had never smoked. Knudson used equipment and techniques that conformed to the American Thoracic Society standards that were in use at the time. Spirometric data were taken with a portable flow pneumotachograph designed especially for the study. Knudson's values were mandated to be used in the OSHA Cotton Dust Standard but are now no longer used.

CRAPO (1981) This study complied most closely with the ATS standards for equipment that was available at the time. The sum of the largest FVC and FEV_1 was used to determine the best curve. The ATS defines a best curve (for measuring flows only) as an acceptable tracing that has the largest sum of the FVC and FEV_1; however, the **largest** FVC and FEV_1 should be used, regardless of the curve(s) from which they are derived. Crapo et al. used the FVC and FEV_1 values from the best curve in their data analysis, instead of the largest FVC and FEV_1 as currently recommended by

ATS. Their population consisted of healthy, well-screened, Mormons living in Salt Lake City, Utah at high altitude who had never smoked.

KNUDSON (1983) The 1976 study was re-evaluated as slight revisions were made after eliminating unacceptable maneuvers. The reanalysis gives LLN's for each sex and age group as well as the prediction equations.

NHANES III (1999) The publication of the NHANES III prediction equations was an important step forward. This was important not only because the reference values are based on a random sample of the U.S. population that was examined but also because predicted values specific for African-Americans and Hispanics, based on randomly selected subjects from the U. S. population, are now available. Test procedures used complied with ATS standards. It is recommended by the American College of Occupational and Environmental Medicine (ACOEM) that their equations be used in the occupational setting. ATS/ERS 2019 Update continues to urge occupational health clinics to continue using these reference equations for longitudinal studies where continuity is important.

The GLI-2012 Reference equations currently provide the most reliable spirometric prediction equations for the 3–95-year age range and include appropriate age-dependent LLNs. The GLI equations have been endorsed by all major international respiratory societies and adopted as the recommended reference equation by many national respiratory societies.

B. Selecting Predicted Values

Some variation exists between the predicted values of the different studies, as illustrated in the hypothetical case study below.

TABLE SHOWING A COMPARISON OF SOME OF THE PREDICTED V ALUES IN USE

The hypothetical subject is a 41 year old white male, with a height of 71" (180.34cm). His observed spirometric values, corrected for BTPS were: FEV_1= 3.14 liters and FVC = 3.92 liters.

The subject's predicted values are calculated from several sources of predicted normal values. Usually a subject's FVC and FEV_1 are considered within the normal range if they are at least 80% of the predicted value. The individual described above would be considered either within or out of the normal range expected for someone of his age, height, and race, depending on which predicted normal values are used.

	FEV_1 PRED.	% PRED.	FVC PRED.	% PRED.
NHANES III 1999	4.03	77.9%	5.2	75.4%
Knudson 1983	4.28	73.4%	5.18	75.7%
Crapo 1981	4.28	73.4%	5.21	75.2%
Knudson 1976	4.07	77.1%	5.07	77.3%
Cherniack 1972	4.04	77.7%	4.90	80%
Morris 1971	3.92	80.1%	5.18	75.7%
Kory 1961	3.93	79.9%	4.87	80.5%

The name and year of publication of the predicted values being used should be recorded each time they are compared to a subject's values. The following guidelines are suggested for selecting which published values to use:

1. Use the predicted normal values that are required by law (or regulations) where applicable, , ACOEM, NIOSH and the ATS/ERS 2019 update recommend NHANES III for general use, though the Global Lung function Initiative (GLI) reference values are recommended at the default set for spirometry systems.
2. All predicted values must be from the same set (e.g., do not use a predicted FVC from one study and a predicted FEV_1 form another study).

3. If predicted values have not been used previously, choose predicted values from studies that use equipment and techniques consistent with spirometry standards of the American Thoracic Society that were current at the time that the study took place.

NOTE: Some Spirometers have one or more sets of predicted normal values programmed into which individual results are compared. The predicteds used are either chosen when the equipment is purchased or are selected from a computer menu. Be sure that the predicted values used by your equipment are the ones you want. At least once, you should verify manually by calculating predicted normal values for FVC and FEV_1 from the published set for a male and a female and comparing the results to the computer printout.

Race Adjustments of Predicted Values

Publication of the NHANES III prediction equations is an important step forward, not only because the reference values are based on a random sample of the U.S. population that was examined in the last few years, but also because predicted values specific for African-Americans and Hispanics, based on randomly selected subjects for the U.S. population, are now available. Until this time, the most widely used reference values have been derived from Caucasian populations in North America. Prior to 1978, when workers in the cotton industry were evaluated using these Caucasian reference values, more abnormal spirometry results were noted among African-American than among Caucasian workers. Since race-specific reference equations were not in general use in 1978, OSHA mandated that "the predicted FEV_1 and FVC for blacks should be multiplied by 0.88 to adjust for ethnic differences". At the time, OSHA recognized that "this correction may not be precisely correct," but OSHA relied on the current state of the art "to provide proper interpretation of spirometry measurements for blacks without inadvertently fostering discrimination in hiring practices." The practice of adjusting Caucasian predicted values for FVC and FEV_1 for African-American subjects has remained widespread in the occupational setting since 1978. However, race-adjustment is less widely used in the clinical setting.

There is less consensus on the adjustment of Caucasian predicted values for other ethnic groups, such as Hispanics, Asians, and Pacific Islanders than there is for African-Americans. Current sources and studies do not recommend race-adjustment for any of these groups except for some Asians, i.e. Chinese and Japanese, in addition to African-Americans.
As noted above, ACOEM recommends that occupational settings consider adopting the NHANES III equations for general use as they become available in spirometry systems. Until these equations are available, ACOEM recommends that Caucasian predicted values should be race-adjusted for African-American applying the ATS recommended scaling factor of 0.88 if permitted by the spirometer software, or else 0.88, to the Caucasian predicted FEV_1, and FVC. For American born Asians, predicted values should be adjust to 0.88. However, if testing is conducted under the few regulations and guidelines that have specific recommendations/requirements regarding race-adjustment factors, those requirements should be followed. For more information on ethnic corrections refer to page 950 of ATS/ERS Standardization of Lung Function; Interpretative Strategies for lung Function tests. Eur. Respir J 2005:26 948-968.

GUIDELINES FOR ASSESSING IMPAIRMENT

Severity of Impairment

Once impairment is determined by LLN, then use FEV_1 percent of predicted to find the degree of severity

Degree of Severity	FEV_1 % Predicted
Mild	> 70
Moderate	60-69
Moderately severe	50-59
Severe	35-49
Very severe	< 35

ATS/ERS Standardization of Lung Function. 2005:

If the FVC and the FEV_1 are above the LLN, the record is normal

If the FVC is above the LLN and the FEV_1/FVC% (ratio) is below the LLN, classify the severity of the obstruction by the FEV_1 percent of predicted.

If the FVC percent of predicted falls below the LLN, then report the degree of restriction by the FVC percent of predicted.

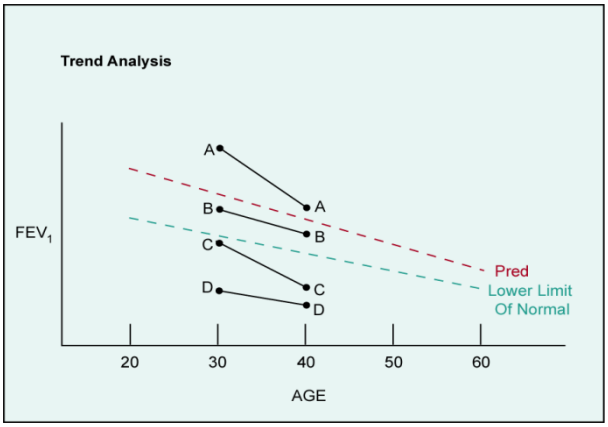
TREND ANALYSIS AS USED IN SURVEILLANCE

Serial Testing and Trend Analysis

Respiratory surveillance programs in the industrial setting usually identify abnormalities by comparing test results with the lower limit of normal from predicted values. This approach is subject to misinformation, as tested individuals frequently fall into the normal range, yet exhibit an abnormal annual decline in lung function. Conversely, the individual's tests results can fall below the normal range but display a perfectly normal annual lung function decline.

The accompanying diagram displays observed values for forced expiratory volume in one second (FEV_1) obtained from four hypothetical test subjects having the same age, height, sex, and race. Test was conducted over a ten-year period.

Trend Analysis



Subjects A and B are within the normal range; Subjects C and D display an abnormal FEV_1. Testing ten years later identifies the following:

> *Subject A* remains at a normal level, but displays an abnormal decline in lung function, indicating a clinically significant current adverse respiratory response.
> *Subject B* exhibits a normal level and decline, indicating no significant past or present adverse response.
> *Subject C* exhibits an abnormal level and decline, indicating significant past and continued adverse respiratory response.
> *Subject D* exhibits an abnormal level, but with a normal decline, indicating significant past but not continued adverse respiratory response.

This example clearly demonstrates how the level of pulmonary impairment, based solely on isolated data without considering annual decline, can result in misinformation. **The clinical significance of both level and decline in lung function pinpoints the need for 1) baseline testing to determine the current level of pulmonary functions, and 2) serial or repeat testing to observe the rate of decline and document the rate of loss.**

COMPARISON SPIROMETRY (TREND ANALYSIS) REQUIRES OPTIMAL QUALITY CONTROL

This article appeared in the Mayo Clinic newsletter "Airflow Update", Mayo Pulmonary Services Vol. 3, No 4, 1988

The serial comparison studies required for longitudinal surveillance in the occupational setting impose the need for much stricter quality control than tests used for diagnostic purposes.

There are two methods of evaluating spirometry results. **Diagnostic spirometry** categorizes an employee at a single point in time as being either "normal" or "abnormal" by comparing his results to those from a group of normal individuals. **Trend analysis** compares his results to his own previous results.

Diagnostic Spirometry. Diagnostic spirometry only requires the results from a single spirometry test and is not affected by minor inaccuracies, but often cannot detect abnormalities early in the course of a chronic lung disease. Even when an employee's age, height, weight, sex and race is matched with a seemingly identical group of "normal" individuals, the range of normal spirometry values is very wide. The normal range of FEV_1 is plus or minus 20 percent of the mean predicted value, therefore, if an employee starts with an FEV_1 of 120 percent of the predicted value he would have to lose one third of his lung function before he would fall below the lower limit of the normal range (below 80% of the predicted value.) Diagnostic spirometry is useful, however, for pre-placement exams and for employees with respiratory symptoms.

Trend Analysis. Comparing an individual to his own previous results is potentially a much more sensitive method of detecting mild abnormalities than waiting for his results to fall below the lower limit of the normal range. **Normally, the FEV_1 decreases by only 30mL per year in adults. A decline of more than 60 ml per year is abnormal, suggesting the development of chronic lung disease. Since a normal adult's FEV_1 is about 3000 ml, a change of only 2 percent (60ml) could be a warning sign.** Ideally, at least 5 data points are preferable to construct a trend.

There are two solutions to the problem of a high intra-individual variability reducing the ability of serial comparisons to detect mild abnormalities of lung function.

1. By testing frequently over a long period of time, the overall downward trend may emerge despite the "noisy", poorly reproducible measurements. Unfortunately, this solution is not only expensive, but the employee's lung function is constantly declining during the extra time that it takes for the trend to be detected.
2. The best solution to the problem is to directly reduce the variability of the measurements. This variability can be substantially reduced by strict consistent quality control of calibration and breathing maneuvers.

SPIROMETRY IN RESPIRATORY SURVEILLANCE PROGRAMS

Spirometry plays an important role in a respiratory surveillance program. It is portable, safe for both the subject and the technician, non-invasive, inexpensive, and reproducible. With skilled and experienced staff, it is also relatively simple to perform. Spirometric test results must be evaluated in the context of other medical information to offset its limitations. Respiratory surveillance programs should contain at least the following regularly scheduled components:

1. A detailed health history, with emphasis on smoking patterns, previous lung disease, and current respiratory symptoms.
2. A comprehensive employment history, with emphasis on potential occupational exposures to pulmonary hazards and respirator usage. Information should also be sought on potential exposures from hobbies, recreational activities, and part-time employment.
3. A thorough physical examination, with emphasis on the chest.
4. Chest radiographs (X-rays) where appropriate. It is important to consult with radiologists who have had special training in reading chest x-rays for occupational diseases, such as B-readers. These are physicians trained and certified by NIOSH to read chest x-rays for evidence of pneumoconiosis.
5. Spirometry.

A respiratory surveillance program should also interface with an industrial hygiene program that identifies and controls potential pulmonary hazards and oversees employee respirator training and fit testing activities.

The frequency with which spirometry is used to monitor workers depends on the level of exposure and the severity of the potential impairment. However, as with every medical test, one must have a clear reason for performing spirometry, and guidelines for interpreting the tests and applying the results.

Medical surveillance itself must be used in conjunction with environmental monitoring and engineering controls to limit, if possible, the amount of exposure. In this context, medical surveillance is really a quality control procedure, designed to detect whether excessive exposure is occurring despite the control procedures in place.

After ruling out technical causes for low or declining pulmonary function, if abnormalities are detected or if a decline in pulmonary function compared with previous tests is detected, efforts must be made to identify the cause. If the cause is a workplace exposure, then steps must be taken to reduce the exposure and prevent further damage to the individual's lungs. It is unethical to use spirometry to detect workers with occupational pulmonary damage if no attempt is made to reduce their exposure or if the information is used as a reason for dismissal.

DATA MANAGEMENT SOFTWARE PROGRAMS

Computerized Data Management Programs are designed to support the following:

- Maintenance of Employee Health records
- Improve Risk Management Control Programs by detecting early changes in spirometry and other measurements and relate to job exposures.
- Reduce Health Care Costs
- Ensure Regulatory Compliance

There are many software programs available from a variety of vendors. Each program automatically transfers data from the spirometer (or other instruments) directly into the desktop computer.

EXPECTED ANNUAL DECLINE IN PULMONARY FUNCTION VALUES

The serial comparison studies required for longitudinal surveillance in the occupational setting impose the need for much stricter quality control than tests used for diagnostic purposes. After the age of 25 years, the FVC and FEV_1 values begin to fall due to age. The average normal rates of decline are listed as follows.

MALE

- 30ml in FEV_1
- 25 ml in FVC

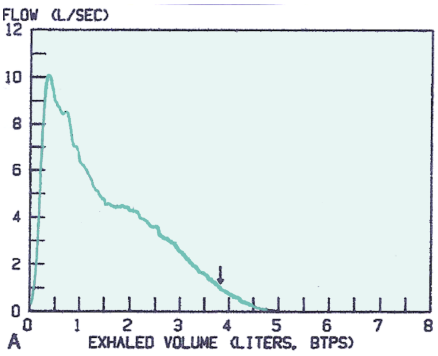
FEMALE

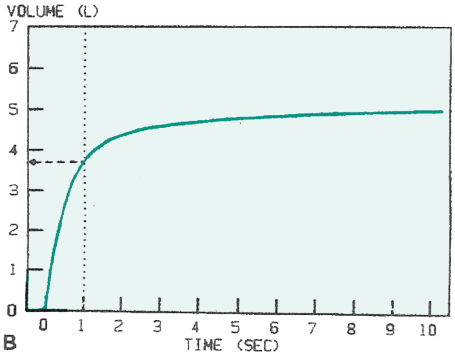
- 25 ml in FEV_1
- 25 ml in FVC

SPIROGRAM INTERPRETATION-PATTERN RECOGNITION

Normal Spirogram

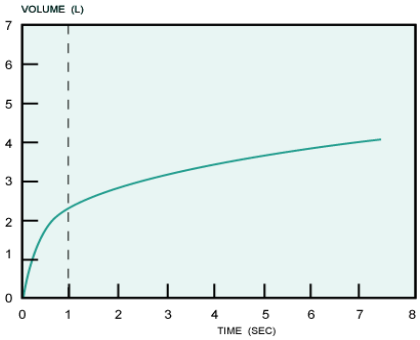
A normal spirogram is marked by the onset of a sharp high peak flow, followed by a sharply declining Phase 2 flow, descending at an angle of approximately 45 degrees if measured at the point representing the end of Phase 2. This is followed by a low flow segment ending at the FVC. On the Volume-Time curve, it is shown as a sharply rising curve with time, terminating in a one second plateau.

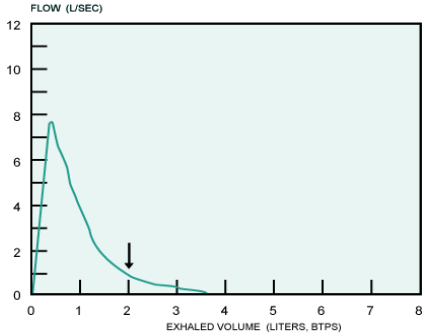




Moderate to Mild Obstruction

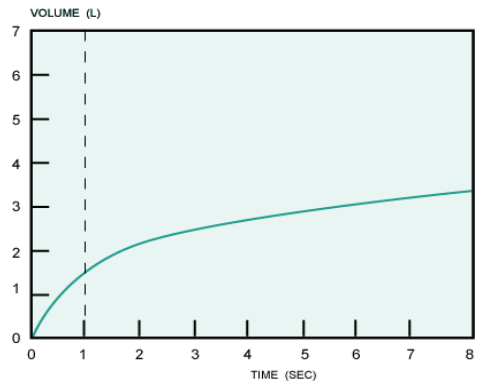
Given that the first air out of the mouth during this test procedure comes from the large airways (trachea and main stem bronchi), it follows that successive airflow comes from airways below that level, until the last air out of the mouth is alveolar. Moderate to small airway obstruction causes the slowing of airflow in the small airways, which is reflected in airflows seen in Phase 2 of the curve after a normal Phase I. Typically the obstruction causes the airflow pattern to appear concave in shape and increase the length of the tail of the curve. It can also be clearly seen on the Volume-Time Curve, that after a normal curve onset, airflow dramatically slows in its climb towards the FVC.

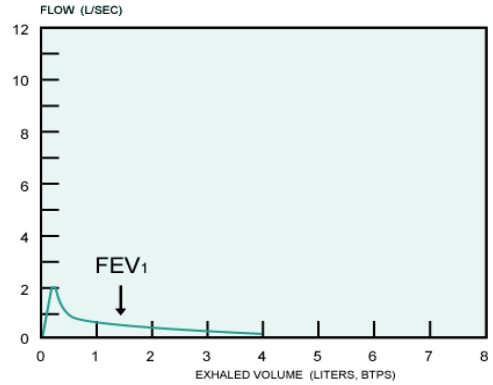




Severe Obstruction

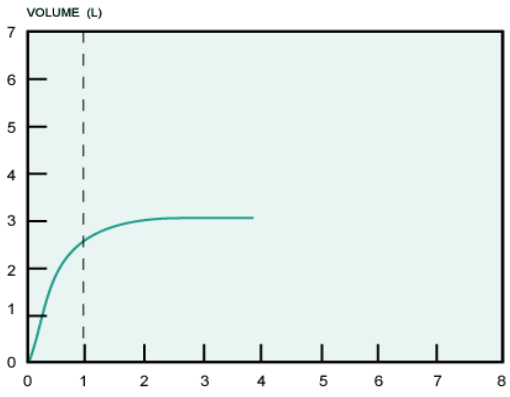
Generally, obstruction develops in the small airways first. Then, as the obstruction progresses, it moves up to the larger airways. As this occurs, Phase 1 is reduced, reflecting the obstruction occurring in the large airways, and is immediately followed by a concave pattern of airflow in Phase 2 of the curve and a prolonged Phase 3 tail. This pattern is often referred to by pulmonologists as the "rat's tail effect".

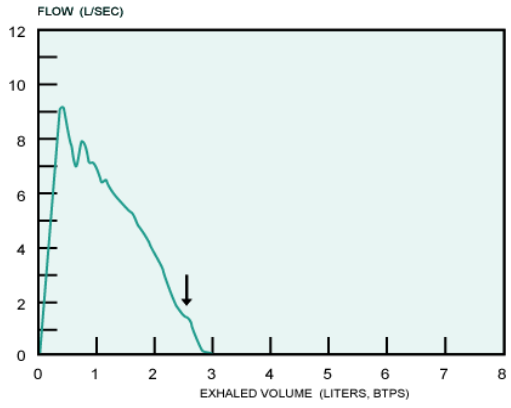




Moderate Restriction

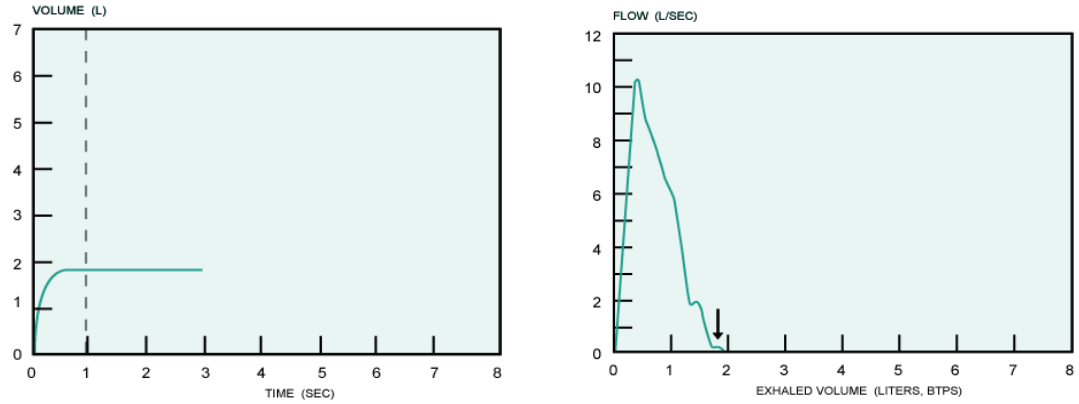
As the restriction develops, due to increasing fibrosis in the lungs, the elastic recoil properties of the alveoli increases, thereby maintaining a high peak flow rate throughout the development of the increasing restriction. As the FVC becomes smaller, the declining flow rate seen in Phase 2 remains linear, but the angle when measured from the Phase 3 onset increased, making a more compressed Flow-Volume Curve. The Volume-Time Curve has all the characteristics of a normal curve with exception that the Volume (FVC) is reduced, thereby giving the appearance of a miniature normal curve.



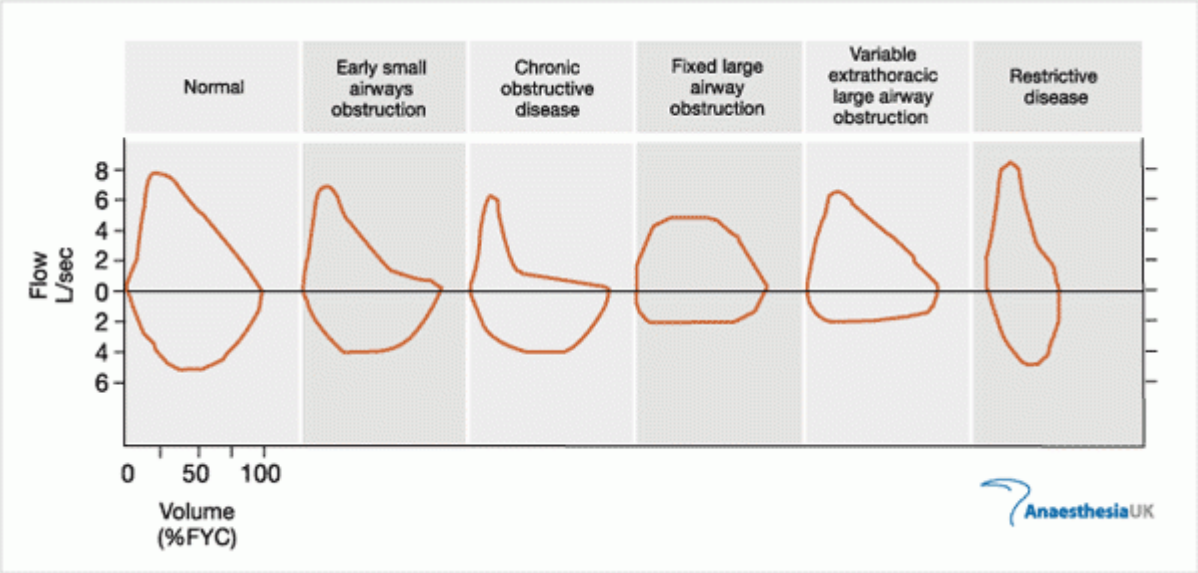


Severe Restriction

It will be noted that there is a sharp high Peak Flow followed by a sharply declining Phase 2, which causes the Flow-Volume Curve to take on the appearance of a church spire or inverted icicle. In every example of abnormality, it should be noted that there are always three distinct phases of the curve present.



Flow Volume Loop Pattern Recognition



Chapter 10

WHEN AND WHERE TO PERFORM SPIROMETRY, RECORD KEEPING, AND CLEANING AND STERILIZATION

ATS RECOMMENDATIONS

Early recognition of lung disease including asthma, chronic bronchitis, emphysema, and black lung disease can only be accomplished by spirometry.

The American Thoracic Society suggests that individuals meeting any one of the following criteria should have at least one spirometry test performed annually or as indicated:

1. Job Pre-placement (Post Offer) Examinations
2. History of shortness of breath upon exertion or at rest
3. History of chronic cough or sputum production
4. History of wheezing or chest tightness
5. History of frequent "colds" or allergic rhinitis
6. Early detection of congestive heart failure
7. Occupational exposure to inhaled dust or chemicals
8. Follow-up visits of all patients with asthma, bronchitis, and other lung diseases
9. Management of all patients on bronchodilators
10. Documentation of pulmonary disability
11. Preoperative for all patients scheduled for thoracic and upper abdominal surgery
12 To evaluate the effects of environmental air pollution
13 Cigarette Smokers over 40 years of age.

SPIROMETRY FOR RESPIRATOR WEARERS

The Respiratory Protection Standard 29 CFR 1910.134

Personal respiratory protective devices (respirators) are required by OSHA and the employer for all employees exposed to dangerous and potentially dangerous, dusts and chemicals in their workplace. Prior to authorization to wear a respirator a medical clearance examination must be given to each worker. Including spirometry as part of this exam although not required, is a prudent addition to the OSHA required medical evaluation for respirator use. Annual medical evaluations which include trending of each individual's spirometry records, and values can provide valuable information regarding the effectiveness of any given respiratory protection program.

Pre placement or post offer spirometry for persons whose jobs require respirators is valuable because an abnormal result may indicate one of the following: 1) the employee has an increased risk of further impairment of lung function or disability if exposed; 2) the employee has a preexisting lung disease not related to the planned work environment; or 3) the employee's lung function is severely impaired so that the small breathing load added by the resistance of the respirator may place a significant and possibly detrimental burden on their cardio-pulmonary system.

In large corporations, less than 3% of all employees (usually smokers with COPD) have moderate to severe airway obstruction. About 15% of employees, however, have borderline to mild airway obstruction; thus, the first two reasons for pre- placement spirometry are most important.

All respirator medical clearance examinations should either include the OSHA mandated questionnaire or a physician administered exam that elicits the same information as the questionnaire. It is recommended that a spirometry test be included also to add sensitivity to the examination. Below is an example of a set of guidelines that physicians use for respirator clearance exams:

Category	FVC % pred		FEV_1 %pred	Abnormality	Respirator use*
I	**>75**	**and**	**>75***	**Insignificant**	**Unlimited**
II	**60-75**	**or**	**60-75**	**Mild**	**Limited**
III	**50-59**	**or**	**40-59**	**Moderate**	**Rare**
IV	**<50**	**or**	**<40**	**Severe**	**Never**

Airflow Update Vol3. No 6.1986 Mayo Pulmonary Services

*And no other abnormalities on other tests

Employees in categories II or III should not be placed in high-risk environments or use respirators for prolonged periods or for heavy exertion.

Employees in Category IV are probably fully disabled because of lung disease and should not work in any job requiring a respirator for protection.

It should be kept in mind when assigning a clearance category to consider the following collateral requirements:

Type of respirator

Anticipated duration of daily use

Level of exertion anticipated during respirator use

Nature of exposure

Special responsibilities

Special environments

Additional protective gear

If the dust or chemical is very toxic, long periods of heavy exertion are expected, or a high-resistance respirator will be used, we also recommend chest x-ray, and ECG (if older than 40 years); and the measurement of changes in blood pressure, pulse rate, and breathing rate while the employee exercises with the respirator. If any of the results are abnormal, consider referral of the employee to a pulmonary specialist who can perform complete treadmill exercise testing which may include the additional following tests:

Exercise testing
MMV maneuver
Arterial blood gasses
Chest radiographs
Other tests as determined by history/screening tests
Observation in the field

After placement, surveillance should be repeated annually and on termination of employment. These serial comparisons will usually allow employees with decrements of lung function to be removed from the risk of further exposures before symptoms or disability occur. (Mayo Pulmonary Services 1986)

CIGARETTE SMOKERS

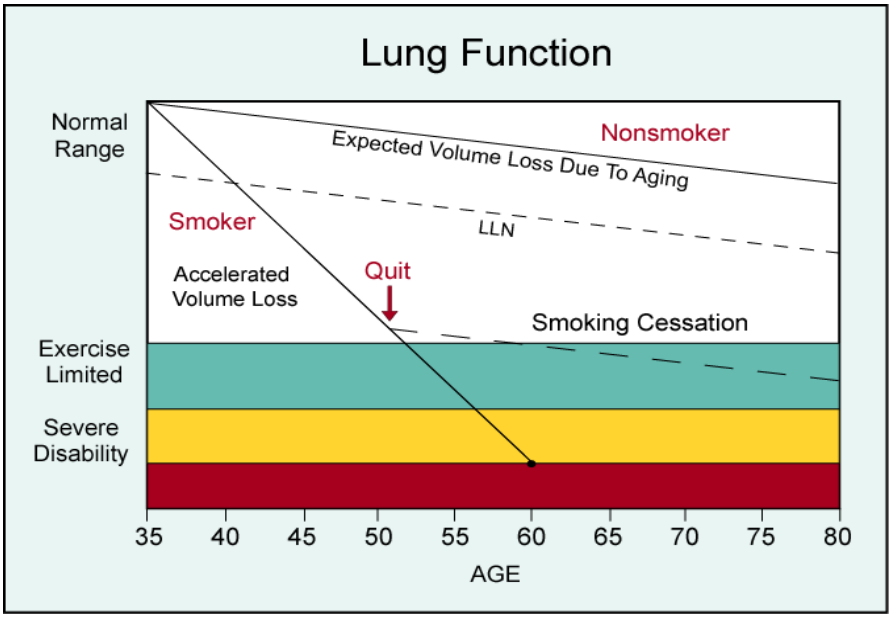
The ATS recommends that those who smoke and are over 40 years of age, should have spirometry performed annually.

Emphysema is the fastest rising cause of disability and death in the United States, eventually affecting about one of every five cigarette smokers. Emphysema progresses very slowly over a period of more than 20 years, and there are no signs or symptoms in its early stages. The only way to detect emphysema early is to measure a person's lung function using a simple, painless breathing test called spirometry (refer to the lung function diagram below).

Normally, lung function declines slightly as you grow older. This decline is much faster in smokers who are developing emphysema. The results of spirometry become abnormal (below the dotted line) many years before a person's ability to exercise becomes limited by shortness of breath due to emphysema (shaded areas).

When smoking is stopped, your lung function will revert back to the normal rate of decline due only to aging (dashed line). The earlier the abnormality is detected and smoking ceases the sooner this reversion occurs. It has been shown that one third of smokers have abnormal spirometry and that 20% of smokers will stop smoking when shown their spirometry results.

An abnormal result of spirometry does not always mean that you have emphysema; an abnormality can also be caused by asthma, bronchitis, or merely a misunderstanding of how to perform the breathing maneuver. We recommend that you discuss any abnormal result with your private physician.



Paul Earight, M.D. Airflow update Vol 3. No 2. 1986 Mayo Pulmonary Services

TESTING ENVIRONMENTAL CONTROLS

Testing Environment

Physiologic measurements such as spirometry, which require subject concentration and cooperation, vary depending on the environment at the time of the measurement. Temperature, humidity, noise level, light intensity, visual distractions, and relative privacy are a few of the many factors that have been shown to directly influence the results of measurement. Standardization of the testing environment in any plant testing program will be improved by use of a temperature regulated examination room located in a quite area.

As stated in the 2019 ATS Spirometry Update, "Testing should preferably occur in a quiet and comfortable environment that is separated from the waiting room and other patients being tested. Drinking water should be available. Tissues or paper towels should be offered to help patients deal with secretions. The patient should be seated erect, with shoulders slightly back and chin slightly elevated. A chair with arms (to prevent falling sideways should syncope occur), without wheels, and with a height adjustment so that the feet are flat on the floor should be used. A smaller chair or a raised footstool should be provided for children and small adults**. If testing is undertaken with the patient in another position, this must be documented in the report**. Tests done while standing are similar to sitting in studies of adults, obesity, and children. Fowler's position (elevated head and torso) yields higher values than supine or Crook's position (knees raised). In most studies involving healthy subjects or patients with lung, heart, neuromuscular disease, or obesity, FEV1 and FVC were higher in more erect positions, whereas for subjects with tetraplegic spinal cord injury, FVC and FEV1 were higher in supine than while sitting.

Do Not Test when ambient temperatures are less than 17C or above 40C, since the ability of the BTPS factor to correct volume may be compromised.
Be sure to check the operator manual for your spirometer model for details about ambient testing conditions.

RECORDKEEPING

Adequate recordkeeping is a critical component of a good spirometry program. To improve the quality of spirometry testing programs, OSHA makes recommendations below on three recordkeeping components: (1) Spirometry test reports, (2) Equipment maintenance records, and (3) Personnel training and evaluation records.

1. **Spirometry Test Reports:** OSHA standards require employers to ensure that medical records for each worker, including the spirometry test results, are maintained for at least 30 years following the end of employment (see 29 CFR 1910.1020).

   Spirometry test reports should include:

   a. Test date and time;
   b. Worker's name, identification number, age, height, gender, and race;
   c. Spirometer used (e.g., type, serial number, etc.);
   d. Ambient air or spirometer temperature and barometric pressure, if appropriate;
   e. Test posture used (sitting or standing);
   f. Source of reference values used (for predicted normal and LLN values);
   g. Test results from at least the three best curves, preferably from all recorded maneuvers, with test sequence indicated;
   h. Technician's name or initials;
   i. Technician comments on worker cooperation/effort or other aspects of the test session;
   j. Flow-volume and volume-time curves for all saved efforts, preferably meeting recommended minimum hard-copy graph sizes (Figure 4b);
   k. A measure of repeatability; and
   l. Date of last calibration check.

2. **Equipment Maintenance Records**: Since equipment maintenance records support the accuracy of the spirometry test results in the medical record, OSHA also recommends saving the equipment records described below. Availability of such records permits later troubleshooting of problematic spirometry test results, which is particularly important when conducting periodic spirometry testing. **Equipment Maintenance Records for each spirometer should include**:

   a. A quality control log which records calibration checks, routine maintenance, upgrades, repairs performed and the results, the date and time of each procedure, and the technician's name. Some computerized spirometry systems store this information in a database. Reports generated during calibration checks should be saved indefinitely; and

   b. The model, serial number, and identification number of the spirometer, and dates and versions of computer software and hardware updates or changes. Store the manufacturer's manuals, warranties, etc. with the quality control log.

3. **Personnel Training and Evaluation Records**: OSHA also recommends that personnel qualifications be documented and available for review.

Personnel Training and Evaluation Records should include:

a. Records of technician continuing education and results of evaluation and feedback to technicians; and

b. Certificates from completed NIOSH approved spirometry training course

CLEANING AND STERILIZATION AND PROPER USE OF SENSORS & FILTERS

- **Wash** your hands before testing each employee and after or use an approved hand sanitizer. Washing your hands is required whether you wear gloves for each patient or not.

- **Use a new filter and mouthpiece** for each subject. Keep the wrapped disposable mouthpiece-sensors or filters in a sanitary box. **Wear a clean glove for each patient** or leave the wrapper on the mouthpiece while attaching the mouthpiece to the spirometer. Do not handle subject's clean or used mouthpiece-sensor.

- **Stand to the side of the patient –** never allow the subject t blow in your face.

- **Wear fit tested N95 filtering face**-pieces when required or is company policy. (refer to Cal OSHA 5199 for N95 use when performing spirometry in CA)

- **At the conclusion of the test the technician must wear a glove when disposing the used mouthpiece, nose clip, and for wiping down the testing area within a six-foot radius.**

- **Clean and disinfect sensor element on a regular basis.** Wipe down the spirometer unit with a non-alcohol cleaning solution. Be sure to follow the manufacturers cleaning recommendations.

- **If a spirometer hose is used,** have several available at the test station, complete with mouthpiece holder, wrapped in a plastic baggie. The nurse should open bag in front of subject. After use, have subject remove hose and drop it in a basin containing sterilizing solution. After sterilizing, rinse, dry and re-bag.

- **Volume Spirometers** should be cleaned and sterilized on a regular basis using procedures described in 'Spirometer Operations Manual'. You **MUST** use a filtered mouthpiece with a volume spirometer.

For more information of hygiene and infection control, it is described in more detail in the ATS Pulmonary function Laboratory Management and Procedure Manu

Chapter 11

SPIROMETER TYPES & SPECIFICATIONS

A REVIEW OF VOLUME DISPLACEMENT AND FLOW MEASUREMENT SPIROMETERS

In choosing a spirometer, the buyer must be prepared to face a selection of many models, as well as claims and counterclaims about the performance of each. Ultimately, determining which spirometer is most appropriate depends on the proposed usage.

Manufactures must ensure that all spirometers meet the standards contained in the current update of the International Organization for Standardization (ISO) 26782 standards, but with a maximum permissible accuracy error of ±2.5% and a syringe accuracy error rate of 0.5%, for a total volume variability allowed of 3.0%.

Two types of spirometric instruments are commonly used: **volume** displacement units and **flow** measurement units. In the volume-based category, the best known and oldest is the water seal or wet system, characterized by the collection of expired air into a closed system sealed with water, as opposed to a dry system, whereby expired air is collected in either a sealed bellows or a rolling seal device. Both the wet and dry systems can measure volume and flow parameters if connected to appropriate data processors. In contrast, the flow-based units use a transducer to measure airflow and convert the information into volumes and flow rates.

Before choosing a spirometer, several important questions should be asked, the answers to which can guide a buyer to the correct type of instrument for a given application. Where the equipment will be used is an important question since the answer reveals the type and complexity of the pulmonary function tests that will be performed, as well as the daily volume of tests to be expected.
In a pulmonary function testing laboratory, in-depth diagnostic studies are performed using simple and sophisticated closed-circuit re-breathing procedures. In a physician's office, usually only simple screening spirometry is performed. Therefore, a graphic record of the spirogram and its computed measurements is desirable for the physician's immediate use. In an industrial medical department, testing is usually restricted to simple spirometry; however, the data not only serve for clinical care when necessary, but, are also used as part of a surveillance system to detect early respiratory dysfunction. When using trending techniques and acute spirometric testing, care must be taken. However, the software package driving the system is based upon the current ATS/ERS requirements. This means ATS/ERS criteria are used to identify Zero Time (Zt) and the End Forced Expiratory Effort (EOFE), also the selection of the correct trial from which test parameters are reported. It also means that a hard, graphic display of the Volume-Time or Flow-Volume curve is available and scaled accordingly to the ATS/ERS recommendations.

Another desirable program feature is quality control assistance. Some systems come with software packages that identify acceptability and repeatability errors that may be missed by an inexperienced technician. The availability of a Flow-Volume display of the test allows the technician to exercise greater quality control over the test, since it more readily reveals defects in the test procedure than the Volume-Time curve alone. The disadvantage of a flow-volume curve is that hand measurement of timed volume curves cannot be made from the graph directly, unless the graph contains appropriate computer-generated timing marks. When testing requires that the spirometer be moved regularly from one location to another, the accent should be on portability and ruggedness.

The ATS/ERS statement recommends that a variety of calibration routines be undertaken to ensure the continuing accuracy of the system. Since volume- and flow-based systems have differing calibration requirements, the buyer needs to understand fully how to perform a multi-flow calibration check on each system.

Whether the spirometer can be easily cleaned takes on great importance when higher volumes of spirometry tests are the rule and equipment cleanliness is a daily prerequisite to avoid the potential for cross contamination.

Key Specifications

- **A spirometer must be capable of accumulating volume for at least 15 seconds and measure volumes up to 8L with an accuracy of ± 2.5% or 0.05L whichever is greater. Also, it should be capable of measuring flow rate of up to 14L/sec with a total resistance of no more than 1.5cm H_20 L/sec.**

- **Graphic Displays of both the Flow-Volume (F/V) and Volume-Time (V/T) curves are required for quality control of the test. F/V curves provide detail for the initial portion of the curve and the V/T curve of the latter part of the curve.**

- **In Spirometry graphs of volume, the scale must be >10mm/L. For screen displays, 5m/L will suffice.**

- **The time scale should be >20mm/sec**

- **When the Volume-Time plot is used in conjunction with a flow-volume curve (both curves are provided for interpretation) & no hard measurements are required, the time scale requirement is reduced to 10mm/sec.**

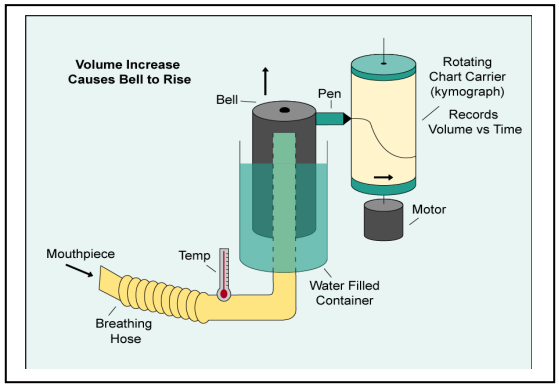
With the above considerations defined, it is possible to examine the types of spirometers available, keeping in mind the benefits each has to offer for specific testing needs.
A complete listing of performance specifications is given on page 332 of the ISO 27682 Standard.

VOLUME DISPLACEMENT SPIROMETERS

Water Seal Spirometer

In 1846, the measurement of static lung volume became possible with the advent of the first spirometer that measured the bellows function of the lung. This device was developed by an English physician, John Hutchinson, MD, who undertook the task of measuring the vital capacity of 2,130 normal men. By adding a graph fastened to a revolving drum (kymograph) to the water seal spirometer, it became possible to measure dynamic lung volumes. This modification, developed in 1947 by Tlffeneau and Pinelli, and by Gaensler in 1951, allowed for the measurement of timed volumes.

The water seal system was perhaps the most common spirometer in use for many years and was the basic unit in any pulmonary function laboratory. Although still used by the cotton industry and can still be found in some doctors' offices, its popularity has waned in favor of other types of volume spirometers. The configuration of the spirometer consists of a bell suspended in a reservoir of water, the open end of the bell being below the water surface. The breathing hose connects to a tube that terminates in the bell above the water line, so that expired air blown into the bell, being trapped by the water seal, pushes the bell upwards, proportional to the amount of air expired. The bell is connected to a pulley system that moves a pen that inscribes its movement on a rotating Kymograph. There are two types of water seal units in use, one using a metal bell, the other a plastic bell. The lighter plastic bell has less inertia and better lends itself to screening-type spirometry tests. Both systems come with multiple speed Kymographs, thereby lending themselves to dynamic measurements. If the primary use of the spirometer is for screening studies and portability is required, this unit has several shortcomings. The unit is bulky, and because of the water reservoir, has to be emptied when moved. Two other disadvantages of a water system are related to water level, which has to be monitored closely to maintain the correct dead space. Also, the water often becomes contaminated with bacteria and requires frequent changing. For the most part, this type of system requires that calculations be done by hand. However, some models allow for automatic measurement and calculation of the volume and flow spirometric parameters with ability to present those values corrected to BTPS and as percent of their predicted values.

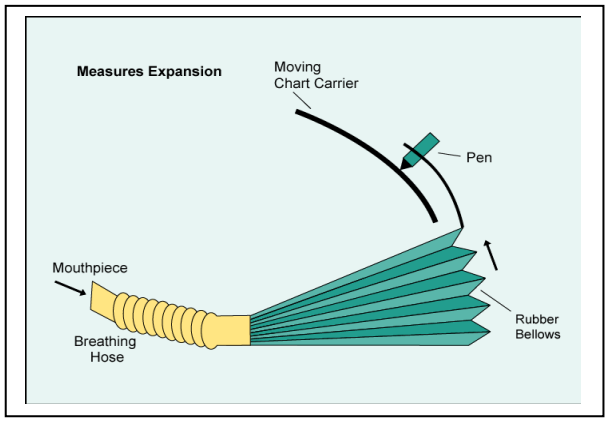


Bellows Spirometer

Because of the inconvenience of maintaining and transporting water-based spirometric systems, an alternative dry volume spirometer design was introduced in the early 1960s, using collapsible bellows. In the same manner that a piano accordion bellows folds and unfolds as air is moved in and out, so does the spirometer bellows move in response to various breathing maneuvers. Bellows designs range from a conventional system suspended either vertically or horizontally within a protective case to a wedge-shaped design where one side of the bellows is fixed, so as the bellows opens, the free side pivots fan-like around the fixed axis. This latter design is by far the most popular since it appears to offer less mechanical resistance than the other systems.

Each of these spirometers comes with a graph transport carriage that moves at a fixed speed, so that Volume-Time graphs can be recorded by a pen mechanically fastened to the bellows. The graph carriage can be activated manually at the beginning of expiration by the technician, or it can be set to start automatically once volume is sensed in the bellows. The latter feature can be useful for screening studies, but care must be taken to see that the triggering mechanism is set to ensure a starting point as close to a back-extrapolation zero time as possible.

Bellows can be made of rubber or vinyl. Some units using the rubber bellows have unusually high resistances due to the stiffness of the material and failed to meet the ATS resistance specification. Bellows system units are tedious to clean in that a sterilizing solution has to be introduced into the bellows, then emptied, rinsed with distilled water, and air dried. Users have observed that repeated cleaning of the system causes the bellows material to become brittle and to crack, thereby introducing leaks into the "fold" areas. Leaks can be repaired using kits from the manufacturer. If the damage is severe, a new set of bellows must be installed.



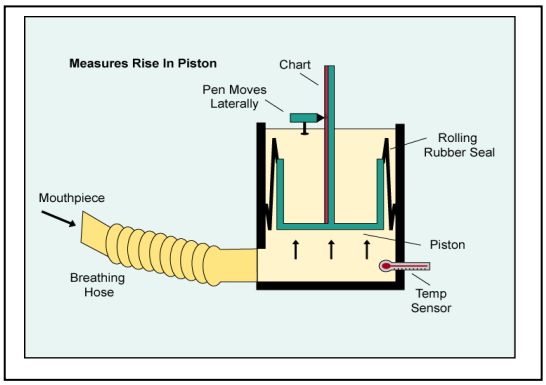
The size of the Volume-Time record varies with each machine, from a marginal 9" x 5" graph to a larger 10 1/4" x 8 5/8 ". Larger graph paper gives more resolution for any hand measurements to be made for close inspection of the FVC signal. Spirographic records are drawn either by a stylus on pressure-sensitive paper, or by use of an ink cartridge. Some

companies offer multiple ink cartridges, which allow each trial to be recorded in a different color to separate and identify multiple trials on the same record.

Bellows spirometers are suitable for dynamic screening tests such as the FVC, or studies of the MVV (Maximum Voluntary Ventilation) and static lung volumes. Many come with microprocessors, either dedicated to the spirometer or non-dedicated, such as personal computers that can be used for other tasks.

Rolling Seal

In the early 1960s, another version of the dry-volume spirometer was introduced and was reported to have the least resistance of any type of volume spirometer, as well as being as accurate as the traditional water seal system. This type of unit consists of a metal cylinder, one end sealed with a piston that moves when air is introduced at the opposite end through a breathing hose. To eliminate friction between the piston and the cylinder wall, and to maintain an airtight system, a silastic rolling seal is positioned to allow the piston to roll upon the seal instead of sliding along the cylinder wall.



In some models, the cylinder-piston assembly is mounted horizontally to minimize the effect of gravity. Such units are often equipped with a spring auto-negator device to return the piston to its zero volume position after an expiratory maneuver. In other units the piston is oriented vertically. The piston moves up when air is introduced into the spirometer and gravity allows the piston to return to its zero position automatically.
The piston's movement can be recorded mechanically or electronically, depending on the make and model purchased. Simple Volume-Time graphs are created by a pen fastened to the piston shaft that inscribes the signal on a moving chart assembly fastened to the spirometer. Alternatively, an electronic flow and volume signal is generated by a potentiometer coupled to the moving piston. This signal can be transmitted to an electronic chart recorder or a personal computer so that flow-volume or Volume-Time curves can be created. Various manufacturers of rolling seal systems provide optional hardware that allows the unit to be used for conducting re-breathing pulmonary function studies.

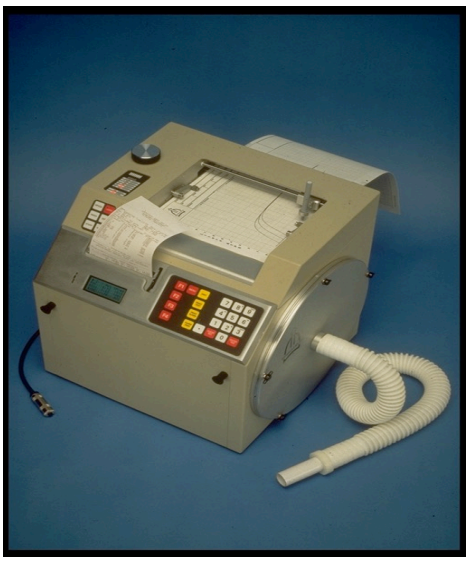
REVIEW OF FLOW MEASUREMENT

SPIROMETERS

Flow Spirometers:

In contrast to a volume-based unit in which expired air is collected in a sealed system, a flow spirometer measures the flow of air through a transducer. Airflow transducers, often called Pneumotachographs (pneumotachs), offer the advantage of being relatively small when compared to a volume spirometer. They are often being smaller than a clenched fist. Besides being compact and portable, pneumotachs are easy to clean and relatively easy to calibrate, although some of them can be challenging to calibrate. They also offer less opportunity for mechanical inertia to reduce the accuracy of the measurements due to the direct processing of the flow signal. Five types of pneumotachs are commonly in use: Fleisch, Screen, Hot wire, Ultrasound, and Turbine.

Volume Spirometer

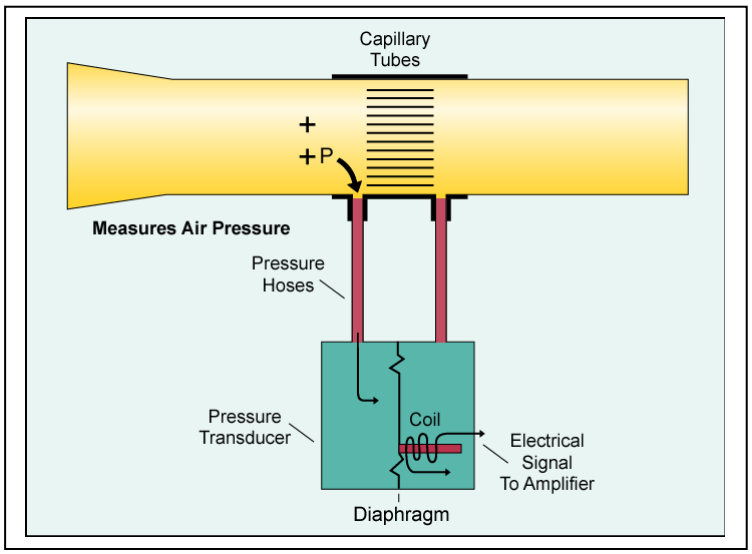


Flow Spirometer

Note how much smaller the Flow Spirometer is than the Volume Spirometer.

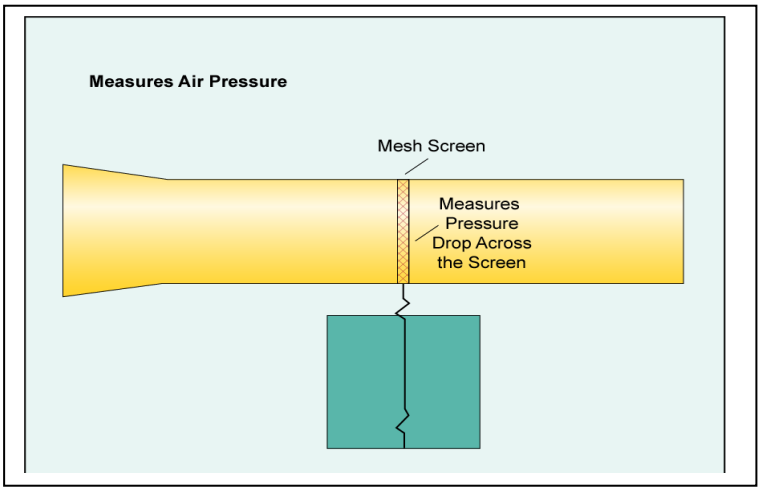
Fleisch:

The original unit and perhaps the most widely used is the Fleisch, which was named after its inventor, the Swiss physician. The pneumotach works on the pressure differential principle, whereby laminar airflow is passed through a resistive element, in this case a group of capillary tubes, and the pressure drop between the pre and post element airflow is measured. An electronic circuit converts the pressure differential into a flow, expressed as liters per second, then by way of an electronic integration circuit, as a volume in liters.



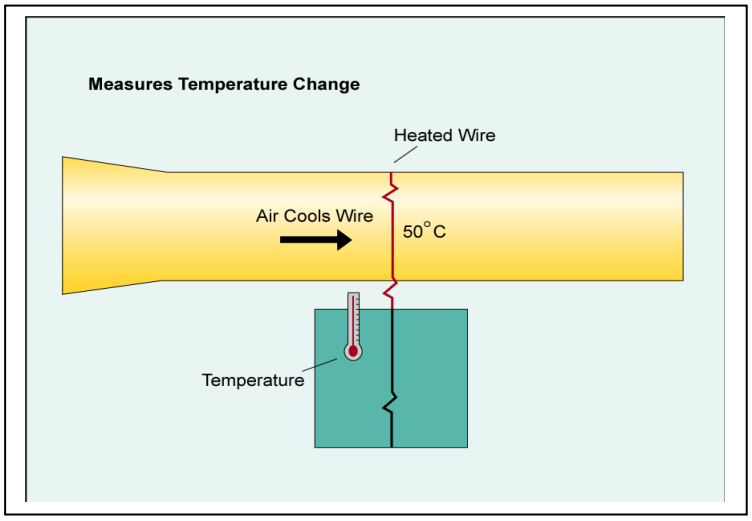
Screen:

A variation of the resistive element principle used by flow spirometer manufacturers is use of a mesh screen which also measures pressure drops across the screen. These range from heated metal screen pneumotachs to fiber screens to allow for the use of disposable sensors.



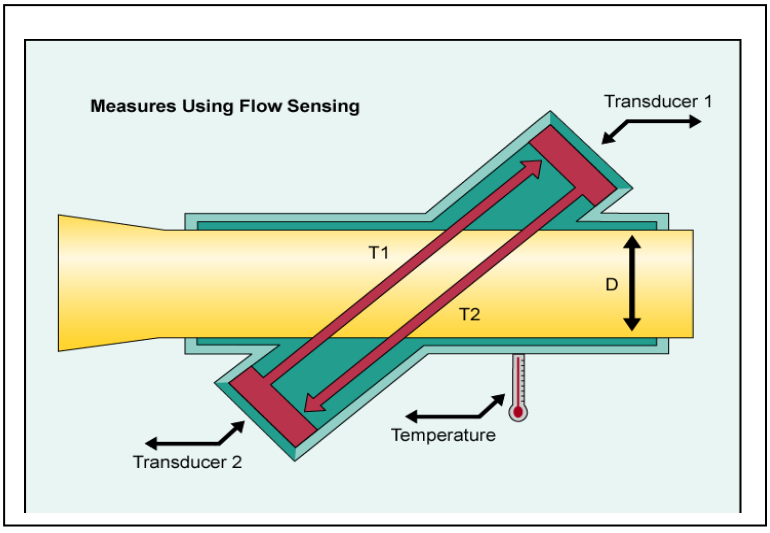
Hot Wire:

The hot wire pneumotach is based upon the principle of the cooling effect of gas flow. Air introduced into the unit flows past a heated wire and causes the wire to cool. An electronic circuit senses the cooling and provides a compensating current to heat the wire and maintain a constant preset temperature. The amount of current used is proportional to airflow and allows for the measure of flow in liters per second and through electronic integration, of volume in liters.



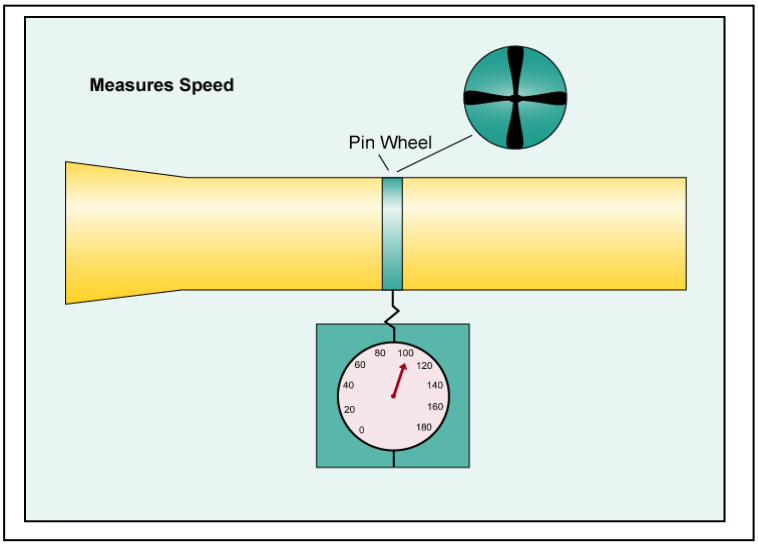
Ultrasound:

The most recent technology is reflected in the ultrasound spirometer. This unit uses the Doppler principle of flow sensing, whereby airflow measure is achieved by measuring the frequency with which sounds waves from an emitter reaches a receiver on the opposite side of the air stream.



Turbine

The Turbine type of sensor works on the principle of a pin wheel. As air is blown through the sensor, a pinwheel spins measuring the airflow speed. An infrared light beam diode located adjacent to the turbine counts the rotation of the blades and that count per second is converted to flow rate, and by integration to volumes.



It is important to note that OSHA/NIOSH does not endorse or approve any particular type of spirometer, only requiring that they meet all the ISO performance specifications. Each type of pneumotach comes with its own strengths and weaknesses. Common to all is the limitation that at very low or very high flow rates, the signal becomes nonlinear. Most flow spirometers have used a pneumotach that accurately measures flow from 0 to 14 L/sec. If a pneumotach system is to be used for measuring static lung volumes when flow rates are low, it may be necessary to have a system that allows for the interchange of flow heads, which would permit the accurate measurements of low flows. Flow spirometers also are suitable for use in pulmonary laboratories for all static, dynamic, and rebreathing pulmonary function tests.

ATS/ERS MINIMAL SPIROMETER PERFORMANCE STANDARDS

1. **Accuracy Volume:** Range 0.5 L – 8 L or within 2.5% of reading or ± 50ml, whichever is greater for:
   - **a.** FEV1
   - **b.** FVC
2. **Accuracy flow:**
   - **a.** PEF: ± 10% of reading or ± 0.300 L/sec
   - **b.** FEF 25-75% range 0-7 L/sec ± 5% or ± 0.200 L/sec
3. **Range:**
   - **a.** Volume: Capable of measuring volume from 0.5 to 8 liters (BTPS)
   - **b.** Flow: 0-14 L/sec
4. **Inertia** and **Resistance:**
   Less than 1.5 cm. H_2O/liter/second at an air flow of 14 liters/second.
5. **Zero - time point determination:**
   "back extrapolation" method or equivalent.
6. **Conversion to BTPS:**
   Instrument or user must have a means of correcting to BTPS.
7. **Graph Requirements:**
   - **a.** Recording of Flow versus Volume and/or Volume verses Time
   - **b.** Paper speed of at least 20mm/second.
   - **c.** Volume sensitivity – at least 10 mm or chart paper per liter of volume.
   - **d.** Flow Sensitivity – at least 5 mm/L/sec
8. **Calibration Requirements:**
   - **a.** Use a 3L syringe
   - **b.** Performed daily, and every time the power is turned on.
   - **c.** **Flow Spirometers:**
     - **Daily,** insert 3 Liter Volume at 3 different rates, i.e. (1 second, 3 seconds, 6 seconds). All must meet ± 3.0% criteria.
     - **Weekly** linearity check. Insert 3L volumes, three times for each of the 3 speeds. All must meet ± 3.0% criteria.
   - **d.** **Volume Spirometers:**
     - Insert a 3 Liter Volume over a period of 2-3 seconds
     - Accuracy must be within ± 3.0% of reading or ± 0.05 Liters whichever is greater.
     - Volume: Linearity check quarterly (See page 323 of standard Appendix 1)
     - Leak Test: Daily
     - Chart Speed: ± 2% of speed; quarterly

GRAPH SIZES

Validation Size Graphs

Volume-Time
Volume: 10mm = 1L (or greater)
Time: 20mm = 1sec (or greater)

Flow-Volume
Volume: 10mm = 1L
Flow: 5mm = 1L/sec

Graphic records are required as permanent records. Graphs can be recorded in two sizes depending on their intended use. Graph sizes are selected from the spirometry configuration menu. Validation size graphs (large graphs) are used when hand measurements are required in legal cases or for social security disability cases. The smaller diagnostic size graphs can be used for routine practice when both the Volume-Time and Flow-Volume curves are present on the same report. If a spirometer is capable of archiving records, then it has the capability to produce the graphs in either size on demand to fit the circumstance. If there is no archiving capability on a spirometer, then it would be preferable to provide graphs in validation size only as the permanent records, should those record ever be required for legal review.

The graph dimensions for diagnostic size are listed as follows:

Diagnostic Size Graphs

Volume-Time
Volume: 10mm = 1L
Time: 10mm = 1sec

Flow-Volume
Volume: 5mm = 1L
Time: 2.5mm = 1sec

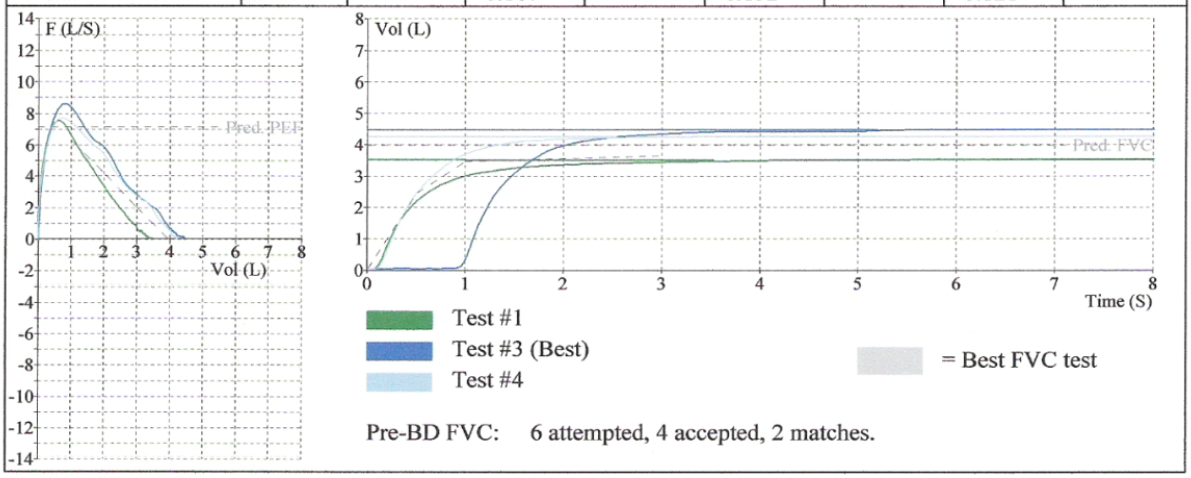
As indicated in the ATS/ERS Standardization of Spirometry 2019 Update on Page e74, under "Display", "For optimal quality control, both volume-time and flow-volume real-time displays are required, and operators must visually inspect the performance of each maneuver for quality assurance before proceeding with another maneuver".

DIAGNOSTIC SIZE GRAPHS

Spirometry Report

Name:		Age:	23 years	Race:	Hispanic
ID:		Height:	65 inches	Weight:	150.0 lbs.
Sex:	Female	Indication:			
Smoker:	No.	Medications:			
COPD Risk:	Low	Lung Age:	< 23 years		
Requested By:		Performed By:	Alan Palmer		
Test Date:	06/29/06 11:23:08	Sensor S/N:			
Press./Temp.	760 mmHg./69 degrees F	Sensor Calibrated:	06/29/06 10:46:28		
Bronchodilator:		Normals/Interp.:	NHANES III/ATS (1991)		

Measurement	Units	Predicted	Pre-Bronchodilator Trial					
			1		3		4	
			Actual	% Pred.	Actual	% Pred.	Actual	% Pred.
FVC	L	3.949	3.477	88 %	4.443	112%	4.246	107%
FEV1	L	3.435	3.037	88 %	3.911	114%	3.798	111%
FEV1/FVC	%	87 %	87 %	100%	88 %	101%	89 %	103%
FEF25%	L/S	6.392	7.266	114%	8.232	129%	7.223	113%
FEF50%	L/S	4.311	4.134	96 %	5.333	124%	5.238	122%
FEF75%	L/S	2.106	1.670	79 %	2.219	105%	2.468	117%
FEF25-75%	L/S	3.936	3.597	91 %	4.312	110%	4.368	111%
PEF	L/S	7.171	7.611	106%	8.653	121%	7.759	108%
Exp. Time	Sec.		5.600		5.200		4.250	
V ext.	L		0.107		0.152		0.121	



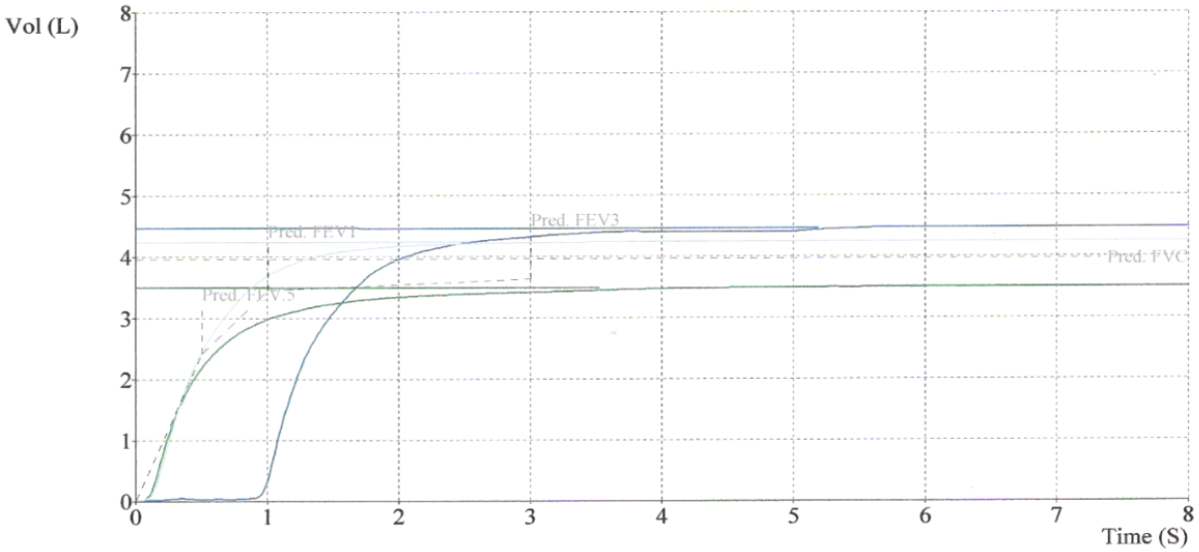
Interpretation: Normal spirometry.

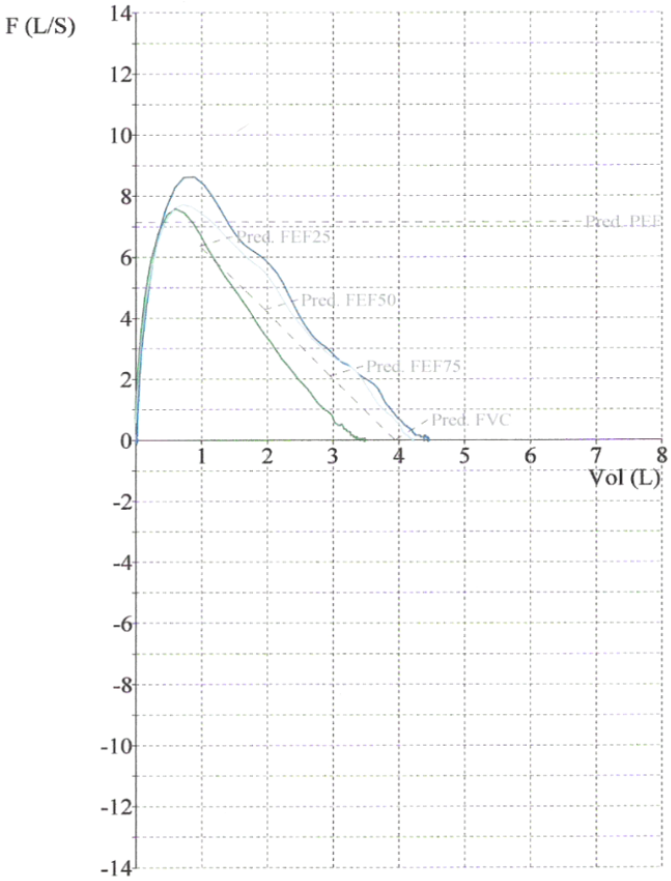
Unconfirmed Report

VALIDATION SIZE GRAPHS

Name:
ID:
Test Date: 06/29/06 11:23:08

Best 3 Pre-Bronchodilator FVC Tests





Test #1
Test #3 (Best)
Test #4

Pre-BD FVC: 6 attempted, 4 accepted, 2 matches.

Midmark Diagnostics Group Software Version: 7.0.1 Printed: 06/29/06 11:27:32 Page 2 of 2

EXAMPLES OF SPIROMETER TYPES BY MANUFACTURER

VOLUME SPIROMETER

Directly accumulates and measures the volume of expired air in a closed system. Examples area:

1. Water-seal (Collins)
2. Dry rolling-seal (Spirotech, SensorMedics)
3. Bellows (Vitalograph, Jones)

FLOW SPIROMETER

Measures Flow rate through an open system, then converts flow rate to volume.

1. Fleisch:
   Metal (Vitalograph, KoKo)
   Ceramic (CDX)
   Disposable (CBI, Brentwood-IQ Mark)

2. Screen (Welch-Allyn/Schiller, Renaissance)

3. Hot-wire (Sensor-Medics)

4. Rotameter (Micro-Medical, Futuremed)

5. Ultrasound (NDD EasyOne), Benson

APPENDIX

CONTENTS

- ATS/ERS SPIROMETRY 2019 UPDATE APPENDIX 1
- ACOEM GUIDANCE STATEMENT - 2020 APPENDIX 2
- OSHA – SPIROMETRY TESTING IN OCCUPATIONAL HEALTH PROGRAMS … APPENDIX 3
- REVIEW OF OCCUPATIONAL HAZARDS….. APPENDIX 4
- SPIROMETRY FOR CHILDREN….. APPENDIX 5
- LATEST PUBLICATIONS ….. APPENDIX 6