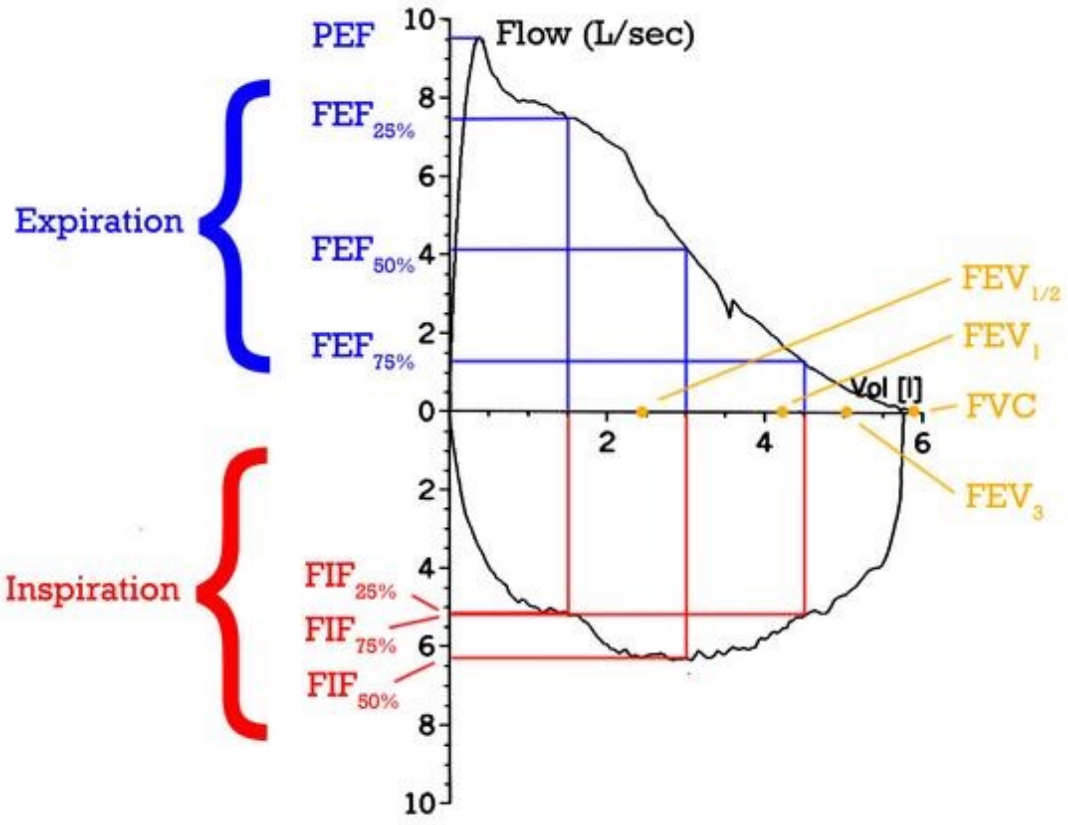
MD SPIRO
a Micro Direct company

25 year ANNIVERSARY 1993-2018 Micro Direct

Office Spirometry Guide



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Why should you perform spirometry in your office?

1. **Your Office sees patients with indications for spirometry** (See Indications for Spirometry)

   The US government carries out studies to gather data about the impact of COPD around the country and report these statistics.[1-3]

   - ✓ Over 16 million US adults have a diagnosis of COPD.
   - ✓ About 9 million US adults were diagnosed with chronic bronchitis in 2017.
   - ✓ About 3.5 million US adults were diagnosed with emphysema in 2017.
   - ✓ COPD is the fourth most common cause of mortality in the US, as well as the fourth leading cause of disability.

   According to the Allergy and Asthma Foundation of America, every day in America:

   - ✓ 40,000 people miss school or work due to asthma;
   - ✓ 30,000 people have an asthma attack;
   - ✓ 5,000 people visit the emergency room due to asthma;
   - ✓ 1,000 people are admitted to the hospital due to asthma;
   - ✓ 11 people die from asthma;
   - ✓ 1 out of 4 American will die from asthma and allergies.

2. **Office spirometry is cost effective and generates revenue** (See CPT Codes)

   Office spirometry is third party reimbursable with an average reimbursement of $37 for a simple five minute noninvasive test.

   The average primary care physician performs 10 tests per week and pays for their equipment in two months or less.

3. **Equipment ease of use**

   Unless the equipment is easy to use, it will not be fully utilized by your staff.

   All Micro Direct spirometers are menu driven via a large graphic display and the test takes less than five minutes to perform.

   The equipment performs all of the calculations, test quality control checks, and provides a confirming diagnostic interpretation.

4. **All Micro Direct spirometers are backed by a 30-day money back guarantee and supported by our team of spirometry experts.**

Only Micro Direct offers five different models priced from $695 to $2,295 and the expertise to help you choose the right spirometer and to fully support your staff from proper testing technique through billing questions.

1. Croft JB, Wheaton AG, Liu Y, et al. Urban-Rural County and State Differences in Chronic Obstructive Pulmonary Disease — United States, 2015. MMWR Morb Mortal Wkly Rep 2018;67:205–211. Accessed April 15, 2019.
2. COPD National Action Plan. National Institutes of Health. https://www.nhlbi.nih.gov/sites/default/files/media/docs/COPD%20National%20Action%20Plan%20508_0.pdf. Published May 22, 2017. Accessed April 15, 2019.
3. National Center for Health Statistics: Chronic Obstructive Pulmonary Disease. National Institutes of Health. https://www.cdc.gov/nchs/fastats/copd.htm. Published May 3, 2017. Accessed April 15, 2019

Indications for Spirometry

Spirometry was first introduced into clinical medicine in 1846 by John Hutchinson. Hutchinson not only designed the first spirometer but also designated the expiratory vital capacity and developed the original normal standards. He deduced that the measurement of a patients vital capacity could be used to trace, define, and diagnose respiratory and circulatory disorders.

Since then, spirometry has been used extensively to measure lung function capability and to recognize and treat many diseases associated with the impairment of healthy lung functions. Spirometry today provides great insight into the status of any persons health.

Generally speaking, spirometry is a simple diagnostic tool used to define a subject's lung condition. The major indications for spirometry are:

- ✓ To evaluate symptoms, signs or abnormal laboratory tests (i.e. dyspnea, chronic cough, chest tightness/cough during exercise, frequent colds)
- ✓ To measure the effect of disease on a pulmonary function.
- ✓ To assess therapeutic interventions (i.e. bronchodilator or steroid treatment, management of CHF, etc.)
- ✓ To assess preoperative risk
- ✓ To screen individuals at risk of having pulmonary diseases (i.e. smokers, obesity, occupational exposures)
- ✓ To assess the prognosis of a disease
- ✓ To assess health status before enrollment in strenuous physical activity programs
- ✓ To assess patients as part of a rehabilitation program
- ✓ To assess risks as part of an insurance evaluation
- ✓ To assess individuals for legal reasons (i.e. Social Security disability, personal injury lawsuits, etc.)

CPT Codes*

The current Procedural Teminology (CPT) codes defined below are the most common used to describe spirometry procedures performed with the MD Spiro spirometers.

CPT CODE	TEST DESCRIPTION
94010	**Spirometry Complete**, includes graphic record total and timed vital capacity, expiratory flow rate measurement(s) with or without maximal voluntary ventilation
94060	**Bronchodilation Responsiveness,** spirometry as in 94010, pre- and post bronchodilator or exercise
94070	**Bronchospasm Provocation Evaluation**, multiple spirometric determinations as in 94010, with administered agents (e.g. antigen(s), cold air, methacholine).
94200	**Lung Function Test (MBC/MVV)** - Maximum Voluntary Ventilation
94016	**Review Patient Spirometry,** 30 day period of time; physician review and interpretation only
94375	**Respiratory Flow Volume Loop**
95070	**Inhalation Bronchial Challenge Testing**, (not including necessary pulmonary function tests), with histamine, methacholine or similar compounds.
94664	**Bronchodilator Administration,** demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer, meter dose inhaler or IPPB device.

Many Medicare Part B carriers have published Local Medical Review Policies (LMRP) that describe specific coverage guidelines for spirometry procedures. For definitive coverage and payment information, contact your local Part B carrier.

*The material referenced and provided is based upon research current at the time of printing. The final decision of billing for any product or procedure must be made by the provider of care, considering the medical necessity of the services and supplies provided, the regulations of insurance carriers and any local, state or federal laws that apply to the supplies and services rendered. We are providing this information in an educational capacity with the understanding that we are not engaged or rendering legal, accounting or other professional services or advice.

Note that applicable laws, rules and regulations may change. While we will use reasonable efforts to update the guide regularly, this guide should not be relied upon as a current or comprehensive statement of all applicable laws, rules and regulations.

ICD-10 Diagnosis Codes

The following ICD-10 codes support the medical necessity for the use of a spirometer. This information is provided only as a guide and is not intended to replace any official recommendations or guidelines.

Diagnosis	Code		Diagnosis	Code
Acute Bronchitis	J20.0-J20.9		Cystic Fibrosis with Pulmonary Manifestations	E84.10
Allergic Rhinitis, Other	J30.81-J30.89		Bronchiectasis	J47.0-J47.9
Allergic Rhinitis, Unspecified	J30.9		Encounter for Preprocedural Respiratory Examination	Z01.811
Vasomotor and Allergic Rhinitis	J30.0-J30.5		Other Interstitial Pulmonary Disease with Fibrosis in diseases classified elsewhere	J84.17
Asthma, Mild, Intermittent	J45.20-J45.22		Other Specified Interstitial Pulmonary Disease	J84.89
Asthma, Mild, Persistent	J45.30-J45.32		Interstitial Pulmonary Diseases, Unspecified	J84.9
Asthma, Moderate, Persistent	J45.40-J45.42		Pneumoconiosis Due to Asbestos and Other Mineral Fibers	J61
Asthma, Severe, Persistent	J45.50-J45.52		Pneumonitis	J67.0-J67.9
Asthma, Unspecified	J45.901-J45.909		Pulmonary, Fibrosis	J84.10
Cough Variant Asthma	J45.991		Respiratory conditions due to inhalation of chemicals, gases, fumes and vapors	J68.0-J68.9
Other Asthma	J45.998		Respiratory conditions due to unspecified external agent	J70.9

ICD-10 Diagnosis Codes (Continued)

Diagnosis	Code		Diagnosis	Code
Sarcoidosis of the Lung	D86.0		Other Long Term (Current) Drug Therapy	Z79.899
Sarcoidosis of the Lung with sacoidosis of the lymph nodes	D86.2		Shortness of Breath	R06.02
Bronchiolitis, Acute	J21.0-J21.9		Systemic Sclerosis with lung involvement	M34.81
Bronchitis, Not Specified as Acute or Chronic	J40		Contact with and (suspected) exposure to environmental tobacco smoke (acute) (chronic)**	Z77.22
Bronchospasm, Acute	J98.01		Nicotine Dependence**	F17.200-F17.299
Bronchospasm, Exercised Induced	J45.990		Tobacco Use (NOS)**	Z72.0
Chronic Bronchitis, Simple	J41.0-J41.8		Occupational exposure to environmental tobacco smoke**	Z57.31
Chronic Bronchitis, Unspecified	J42		Personal history of nicotine dependence**	Z87.891
COPD	J44.0-J44.9		Smoking (tobacco) complicating pregnancy, childbirth, and the puerperium**	O99.330-O99.335
Cough	R05		Wheezing	R06.2
Emphysema	J43.0-J43.9			

**Use additional code after the primary diagnosis to identify any tobacco use, dependence or exposure to tobacco smoke

Spirometry Income Generator

Spirometry Complete 94010	Microlab	Pneumotrac	SpiroUSB	Micro 1
How many spirometry test will you do per week?	10	10	10	10
National average reimbursement for 94010:	$31.00	$31.00	$31.00	$31.00
Purchase price of new spirometer:	$2,295.00	$1,950.00	$1,795.00	$695.00
Your investment will be paid for in (months):	1.7 months	1.5 months	1.3 months	<1 month
Monthly income generated from performing Spirometry:	$1,343.33	$1,343.33	$1,343,33	$1,343.33

Brochodilation Responsiveness 94060				
How many spirometry test will you do per week?	10	10	10	10
National average reimbursement for 94060:	$53.73	$53.73	$53.73	$53.73
Purchase price of new spirometer:	$2,295.00	$1,950.00	$1,795.00	$695.00
Your investment will be paid for in:	1 month	<1 month	<1 month	<1 month
Monthly income generated from performing Spirometry:	$2,328.30	$2,328.30	$2,328.30	$2,328.30

Information Provided by the Spirometer

The standard spirometry maneuver is a maximal forced exhalation (greatest effort possible) after a maximum deep inspiration (completely full lungs). MD Spiro spirometers offer over 30 indices along with graphic representation which includes a volume-time curve and a flow-volume loop. The following indices are the most important indices according to the ATS/ERS standards:

FVC Forced Vital Capacity. Total volume of air forcefully exhaled between the maximal inspiration and maximal expiration. Simply how much air a person can force out of their lungs. This number is displayed in liters.

FEV6 Forced Expiratory Volume at Six Seconds. Volume of air exhaled in the first full six seconds of the maneuver. It is a more recently derived value to help in patients with more severe airflow obstruction. These patients have difficulty and often stop before full exhalation therefore the severity of airway obstruction may be underestimated therefore the FEV6 is used instead of the FVC.

FEV_1 Forced Expiratory Volume at One Second. Volume of air exhaled in the first full second of the maneuver. Simply how much air a person can force out of their lungs in the first second. This number is shown is liters.

FEV_1/FVC Ratio of the FEV1 to the FVC. Percentage of the total volume (FVC) exhaled in the first full second (FEV_1). Also known as FER or FEV1%.

$FEF_{25-75\%}$ Mid Expiratory Flow Rate. Average flow rate over the middle portion of the maneuver. Least effort dependent and may indicate small airway obstruction. Also known as MMEF.

How to Perform a Spirometry Test

Before starting an FVC test session:

Ensure that the patient is fully prepared: posture (sitting is recommended); removable false teeth have been removed; tight clothing is loosened and proper instruction on the test is given - including a demonstration by the operator. Fit a new SpiroSafe filter, MicroCheck mouthpiece or regular cardboard mouthpiece and finally fit a disposable nose clip (optional).

The FVC test can be performed using two methods. Give and demonstrate instructions to the subject so that testing is performed properly:

Method 1 - Single Breath FVC (recommended):

1. Inhale as deeply as possible with the transducer well away from the mouth, insert the mouthpiece, clamping it between the teeth and closing the lips around it to create a perfect seal.
2. Exhale as hard and fast as possible for as long as possible.
3. Optionally at the end of expiration, inhale fully.

Method 2 - Multi Breath FVC:

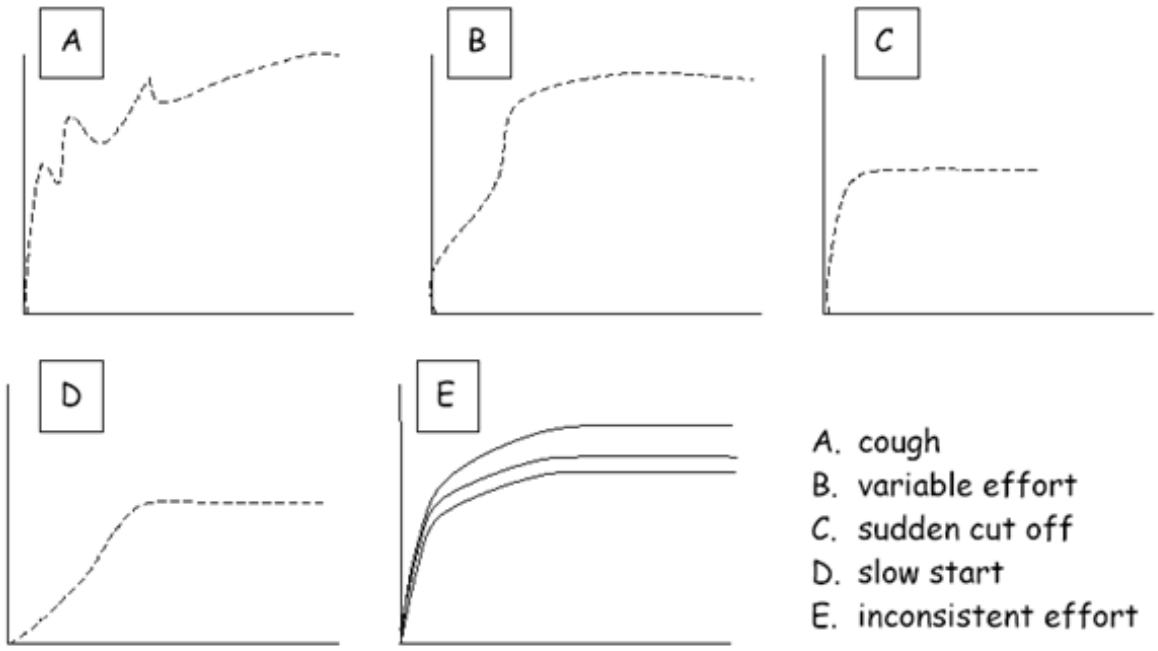
Insert the mouthpiece, clamping it between the teeth and closing the lips around it to create a perfect seal.

1. Breathe in and out normally through the transducer. This is tidal breathing.
2. When happy that the subject has achieved steady tidal breathing, continue
3. Exhale as much as possible
4. Inhale as much as possible (speed is not important) and when fully inhaled
5. Exhale as hard and fast as possible for as long as possible.
6. Optionally, return to tidal breathing.

The Micro Direct spirometers will display the graphs and provided a blow quality to assist you in determining if the effort is acceptable.

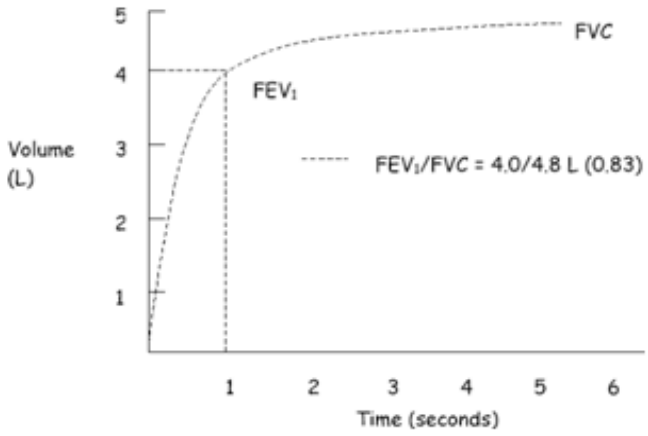
With either method, the procedure should be repeated at least twice until three acceptable and repeatable blows are obtained. The best two of these readings should be within 150 mL or 5% of each other and best. The Micro Direct spirometers will display a message once this criterion has been achieved.

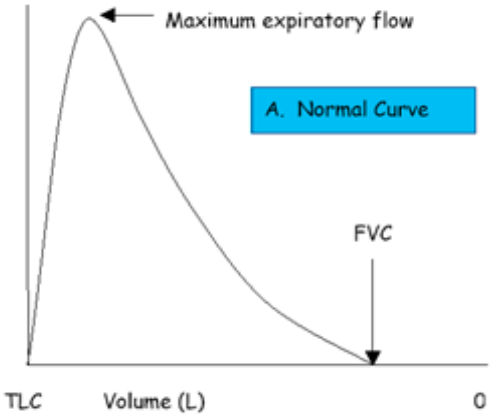
Examples of Poorly Performed Test



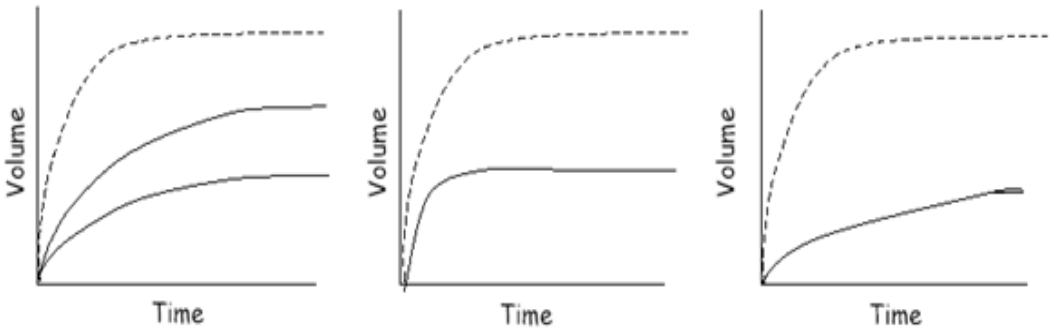
Examples of Spirometric Graphs

Normal Spirograms



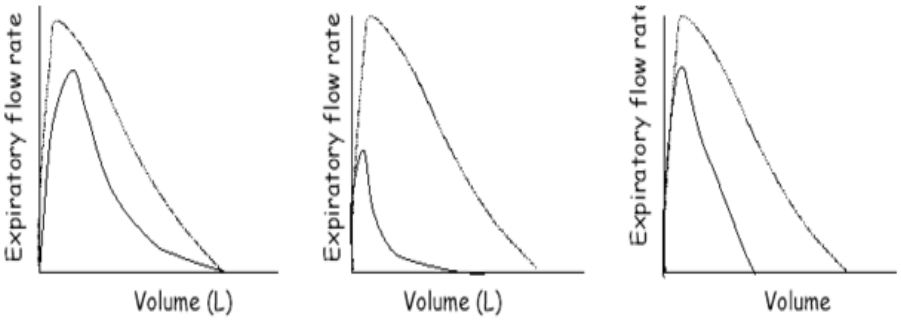


Obstruction Restriction Mixed



- - - - - - Normal ---------Abnormal

Obstruction Severe Obstruction Restriction



- - - - - - Normal ---------Abnormal

Need Additional Information or Support

Micro Direct has been the spirometry leader in the USA for over 25 years and our customer service and spirometry knowledge is second to none.

Please contact us and we would be happy to assist you in any way we can.

Micro Direct, Inc.
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Repair/Service Email: service@mdspiro.com

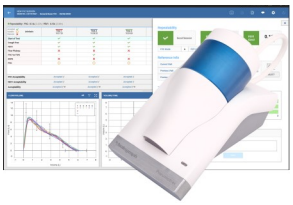
Spirometry Solutions from Micro Direct, Inc.

Your Spirometry Specialist

Alphs (MD6000)
Desktop

- Accurate, Stable Fleisch Pneumo-tach
- Updated Test Quality Grading Sys-tem
- Meets 2019 ATS/ERS Standards
- Live Testing Prompts
- GLI Predicted Equations with LLN & %Pred
- Automatic Interpretation based on ATS/ERS & GOLD Standards
- Clear, Easy-to-Read Report
- Pre/Post Bronchodilator Comparison
- PDF Report Generation Software
- Autoclavable Flow Head
- Complete with Durable Carry Case
- 5-Year Warranty if registered within 30-days of purchase

Pneumotrac (MD6800)
PC-Based



- Accurate Stable, Fleisch Pneumotach
- Supplied with SpiroTrac 6 PC Software
- Meets 2019 ATS/ERS Standards
- Real Time FV Loop or VT Curve
- Choice of Child Friendly Incentives
- 8 1/2" x 11" Printout
- Pre/Post Bronchodilator Comparison
- Automatic Interpretation based on ATS/ERS & GOLD Standards
- Clear, Easy-To-Read Reports
- GLI predicted equations and Z-scores.
- On-Screen Test Quality Prompts
- Autoclavable Flow Head
- Comes with Connect Software for EMR Connection
- 5-Year Warranty if registered within 30-days of purchase

Micro 1 (MS10)
Hand-Held

- Measures and displays FEV_1, FVC, PEF, FEF_{25-75}, FEV_6, FEV_1/FVC, FEV_1/FEV_6, FEF_{25}, FEF_{75}
- Choice of NHANES or GLI Predicted Sets
- Confirming diagnostic interpretation
- Post bronchodilator comparison
- PC software generates PDF for EMR and printing
- Variation from norm as percentage or z-score
- Optional NHLEP mode
- Maneuver quality checks
- Quick test mode
- 2-Year Warranty

Spiro✓ (MD02)
Screening

- Measures and Displays FEV_1, and FEV_1 % Predicted
- 'Lung Age' Estimation
- Quick and Easy to Use
- Large Graphical Display
- Standard 30 mm OD Mouthpiece
- 1-Year Warranty

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