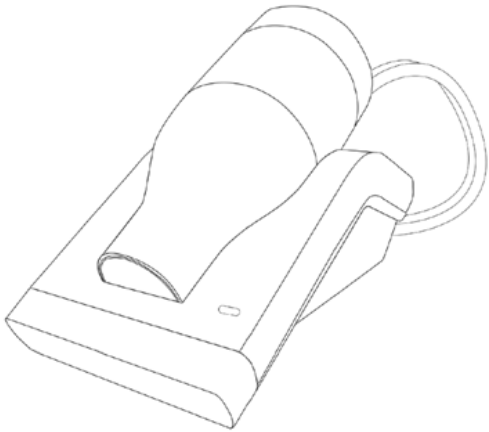
MD SPIRO
a Micro Direct company

Pneumotrac

Model MD6800



Instruction for Use

Current Edition (Issue 2, 27-Jul-2020) Cat. No. 09000

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Indications for Spirometry

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 person's health.

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

- ✓ Dyspnea (shortness of breath)
- ✓ Exercise induced coughing
- ✓ Chest tightness
- ✓ Smokers over 45 years of age (NLHEP recommendations)
- ✓ Obesity
- ✓ Pre-operative testing
- ✓ Occupational exposure to dust and/or chemicals
- ✓ Ongoing assessment of patients receiving bronchodilator treatments
- ✓ Determination and/or documentation of pulmonary disability
- ✓ Asthma diagnosis
- ✓ Pre-existing pulmonary disease
- ✓ Frequent colds
- ✓ Assessment of congestive heart failure

CPT Codes for Spirometry

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 after bronchodilator with spirometry as in 94010

94150 - Vital Capacity
Total (separate procedure)

94200 - Maximal Voluntary Ventilation
Maximum breath capacity

94375 - Flow Volume Loop
Respiratory Flow Volume Loop

95070 - Inhalation Bronchial Challenge Testing
(Not including necessary pulmonary function tests), with histamine, methacholine or similar compounds.

94464 - Bronchodilator Administration
Demonstration and/or evaluation of patient utilization of an aerosol generator, nebulizer and meter dose inhaler or IPPB device

Diagnosis and ICD-10-CM Codes on back cover

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1. Main Components of the Pneumotrac

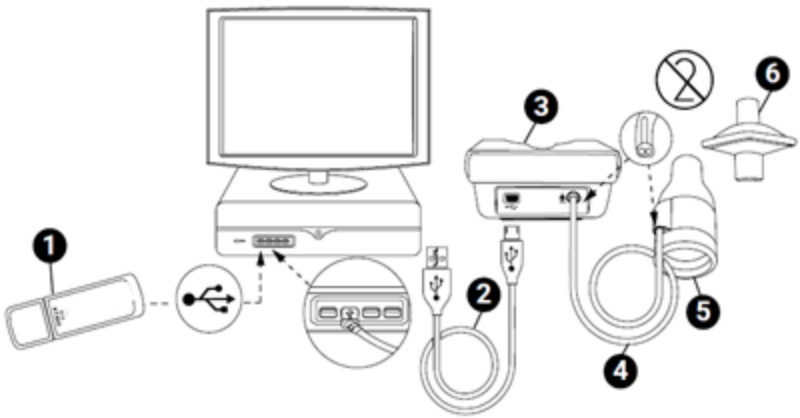


Figure 1 Main components of Pneumotrac

1	USB Flash Drive Containing Spirotrac. Reference *Spirotrac Instructions For Use* for Details
2	USB Cable
3	Pneumotrac Base
4	Flowhead Connection Tubing
5	Flowhead
6	SpiroSafe Viral/Bacterial Filter

Note: Computer not supplied

1.1 Features of the Pneumotrac

- Fleisch type pneumotachograph to measure flow
- Ambient temperature sensor
- USB powered
- LED power indicator
- Soft pouch to store Pneumotrac

2. Setting Up the Pneumotrac

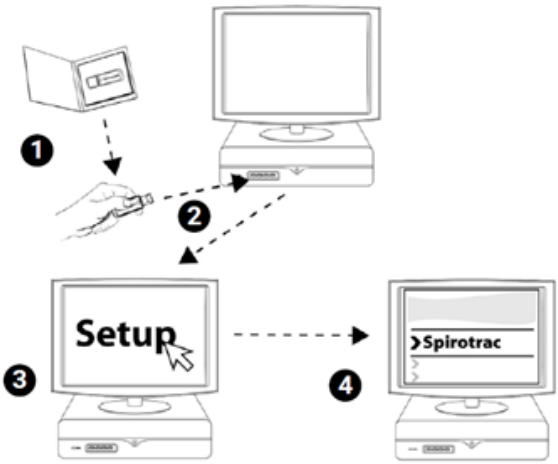


Figure 2

1. Remove USB drive from packaging.
2. Insert USB drive into USB port on computer.
3. Browse USB drive and click Setup.
4. Select Install Spirotrac. Follow on-screen instructions to complete installation. Further details are provided in the *Spirotrac Instructions for Use* supplied with the software.
5. Close installation and select the Spirotrac icon from the desktop.
6. Connect Pneumotrac to the computer using the USB cable (via ports marked with the ⇠ symbol).
7. The green LED on the front indicates power is on.
8. Connect one end of the flowhead connection tubing to the Pneumotrac base.
9. Connect the other end of flowhead tubing to the flowhead.

If the device has just been unpacked or transported, ensure it is left sitting, fully powered to reach room temperature before testing.

3. Operating Instructions

The Pneumotrac works with the Spirotrac software. Spirotrac must be installed on the PC to begin testing. Refer to *Spirotrac Instruction for Use* for details on:

- Installing Spirotrac Software
- Entering Subject Data
- Conducting Spirometry Testing
- Printing a Report
- Calibration Verification

4. Power Management

1. The Pneumotrac device is powered over USB.
2. The green LED on the front of the device indicates that it is powered.
3. The Pneumotrac may be safely powered down by disconnecting the USB cable from the device.

5. Cleaning & Hygiene

5.1 Preventing Cross-Contamination of Subjects

A spirometer is not designed or supplied as a ‘sterile’ device. Micro Direct intends that a new SpiroSafe, viral/bacterial, filter be used for every subject to prevent cross contamination. Using a new SpiroSafe provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry maneuvers.

The interior of a flowhead does not require decontamination where a new SpiroSafe is used for each subject. The outside surfaces of the device and flowhead tube may be cleaned with a 70% isopropyl alcohol impregnated cloth to remove any visible soiling and for low level disinfection.

Where the user suspects the flowhead has become contaminated or where local risk assessment identifies a need for higher level decontamination, then it should be cleaned as per ‘Cleaning and Hygiene’ instructions on the MDSpiro website.

5.2 Inspection of the Pneumotrac

Visual inspection is recommended on a routine basis. Remove the flowhead cone and flowhead end cap from the flowhead (figure 3). Examine flow conditioning mesh filters for damage or contamination. If they are damaged or blocked, discard and replace with new parts. Examine the O-rings on the Fleisch element and replace if damaged. Re-assemble the cone and end cap. It is recommended that an accuracy check is carried out following cleaning and re-assembly as recommended in the ATS/ERS 2019 guidelines.[1]

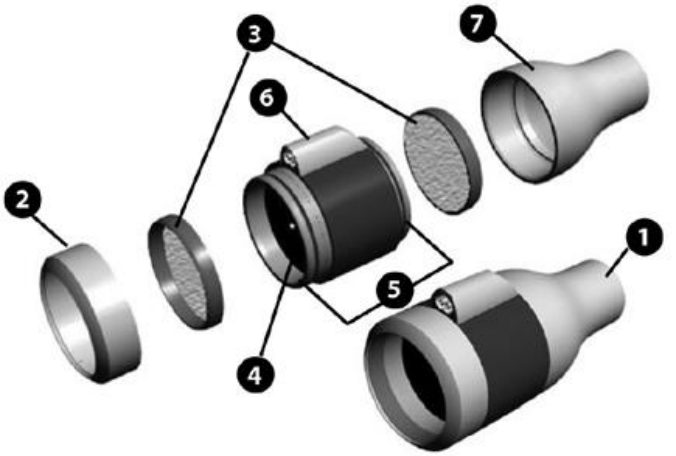


Figure 3: Flowhead Assembly

1	Flowhead Complete
2	Flowhead End Cap
3	Flow Conditioning Mesh
4	Fleisch Element Assembly
5	'O' Rings
6	Pressure Tapping
7	Flowhead Cone
	Lubrication: Silicone Grease

1 Derived from terminology and guidance taken from ATS/ERS Standardization of Spirometry 2019 Update Am J Respir Crit Care Med 2019 Vol 200, Iss 8 pp e70-e88

6. Fault Finding Guide

Problem Fault Symptoms	• Accuracy check variations > ± 2.5% • False readings suspected
Possible Solutions: (In probable order)	• Recheck accuracy (Section Operating Instructions). • Was the correct syringe volume selected? • Flowhead conditioning mesh missing or blocked. • Flow head pressure tapping holes blocked. • Flowhead fleisch element assembly sealing 'O' rings damaged. • Flowhead fleisch element assembly blocked. • Cold syringe – ensure syringe is in its test environment for at least an hour before use. • Internal tubing from pressure ports on device is blocked – contact support. • Electronics failure – contact support.
Problem Fault Symptoms:	• Test begins automatically. • Volume accumulates automatically without the subject blowing. • Very small VC or FVC test displayed.
Possible Solutions: (In probable order)	• Flowhead and/or tubing not stationary at the start of the test. Hold them steady until the 'Blow Now' prompt appears. • Restart the test routine.
Problem Fault Symptoms:	• Rocking Pneumotrac Base.
Possible Solutions: (In probable order)	• Check for damaged or missing feet • If any of the feet are damaged or missing, replace both feet.
Problem Fault Symptoms	• Reversed or no volume measurements
Possible Solutions: (In probable order)	• Ensure tubing is connected correctly. • Ensure the flowhead connecting tube is not pinched or trapped.

7. Customer Service

Service and repairs should be carried out only by the manufacturer or by Service Agents approved by the manufacturer. Contact information may be found on the bottom of this page.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer or its Authorized Representative and the Regulatory Authorities of the country. Refer to the contact information found on bottom of this page

8. Consumables and Accessories

Cat. No.	Description
3385	SpiroSafe Viral/Bacterial Filters (100)
3304	Nose Clips (20)
3325	3-Liter Calibration Syringe
77933	Flow Conditioning Mesh
79192	Flowhead Connection Tube
48-70	Protex Disinfectant Wipe

To place an order for consumables and accessories, for service/repair or for general questions please contact Micro Direct at:

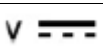
Toll Free: 1-800-588-3381
Telephone: 207-786-7808
Fax: 207-786-7280
Email: sales@mdspiro.com
support@mdspiro.com
Website: www.mdspiro.com

9. Disposal

The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.

Used SpiroSafe filters constitute minimally soiled waste from human healthcare and should be disposed of in line with local requirements. SpiroSafe filters are made from impact polystyrene.

10. Explanation of Symbols

	Type B equipment
	Class II
VA	Power Rating
	Direct Current
	Instructions for Use; operating instructions
	Manufacturer
	Date of Manufacture (include date in format yyyy-mm-dd)
	USB connector
	The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste.
	Fragile, handle with care

	Keep Dry
	Do not-reuse
	Non sterile
	Recycle
	QR code - matrix bar code. All information in the bar code is included in the text under it

11. Device Description and Indications for Use

The Pneumotrac is a spirometer which measures subject respiratory parameters including but not limited to VC, FVC, FEV_1, PEF and MVV. It is designed for desktop use. A Fleisch flowhead is used for testing and has a resting location on the device. The primary indication for the use of the Pneumotrac is the simple assessment of respiratory function through the measurement of dynamic lung volumes, i.e., spirometry in association with Spirotrac PC software by medical professionals trained in respiratory and lung function testing on adults and pediatrics, 5 years and older, in a variety of professional healthcare environments, e.g., primary care, hospitals and occupational health centers

Note: The measurements obtained from a lung function test form part of the various findings of a physician in the detection, diagnosis and control of chest diseases.

12. Technical Specification

Product	Pneumotrac Spirometer
Model	MD6800
Flow Detection Principal	Fleisch type pneumotachograph
Volume Detection	Flow integration sampling @ 100 Hz
Volume Accuracy	Within ± 2.5%
Flow Measurement Range	Max flow rate ± 960 L/min (± 16 L/s) Min. flow rate ±1.2 L/min (± 0.02 L/s)
PEF Accuracy	Within ± 10%
Back Pressure	Less than 0.1 kPa/L/sec @ 14 L/sec (ATS/ERS 2005)
Operating Humidity Range	30% - 75%
Operating Temperature range	ISO26782 limits: 62.6 – 98.6^{o} F Design limits: 50 – 104^{o} F
Ambient Pressure Range	850hPa – 1060hPa
Performance Standards the Pneumotrac Meets or Exceeds	ATS/ERS 2019, ISO 23747:2015 & ISO 26782:2009
Safety Standards	EN60601-1:2006 + A1:2013
EMC Standards	EN 60601-1-2:2015
QA/GMP Standards	EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282, JPAL, MDSAP
Dimensions	6.3” (Length) x 3.75” (Width) x 4.5” (Height)
Weight	1 Pound 3 Ounces
Communications	USB 2.0 / 3.0
Power Supply	5V DC via USB

13. Contraindications, Warnings, Precautions and Adverse Reactions

1. No modification of this equipment is allowed. Any unauthorized changes to the Pneumotrac device may compromise product safety and/or data and as such the manufacturer cannot be held responsible and the device will no longer be supported.
2. The Pneumotrac is not designed as a sterile device. Always follow the safety guidelines given by the manufacturer of cleaning and disinfectant chemicals.
3. For the device to be used as intended, there is no requirement to clean the supporting computer. If cleaning is required to remove visible soiling, this should be done as per the computer manufacturer's instructions.
4. 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 (ATS/ERS 2019).
5. When using the Pneumotrac, ensure the flowhead connecting tube is not pinched or trapped as spirometry results may appear to be inverted.
6. Take care not to block the mouthpiece with the tongue or teeth during testing. A 'spitting' action or cough will give false readings.
7. Subject fatigue may occur during spirometry testing depending on the subject's characteristics e.g., age, health status. For safety reasons, testing should be preferably done in the sitting position, using a chair with arms and without wheels. Subject may also take a break between tests.
8. All values displayed are expressed in BTPS values.
9. Time zero is determined using the back-extrapolated method, from the steepest part of the curve.
10. Do not expose the Pneumotrac to liquids.
11. The Pneumotrac should not be used in the presence of flammable liquids or gases, dust, sand or any other chemical substances.
12. All spirometry standards recommend checking the accuracy of lung function measuring devices daily with a 3-L syringe to validate the instrument is measuring accurately. The Pneumotrac should never be outside accuracy limits. Accuracy should be checked after cleaning or disassembling the spirometer for any reason, after adjusting calibration or if the flowhead or device has been dropped.
13. Service and repairs should be carried out only by the manufacturer or by Service Agents specifically approved by the manufacturer.

14. Maintenance must not be performed while the device is in use by a subject.
15. Use of accessories or cables other than those specified or provided by the manufacturer for this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Pneumotrac and result in improper operation.
16. Non-medical equipment must be kept outside the subject environment i.e., any area in which intentional or unintentional contact between the subject and parts of the system can occur.
17. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 mm) to any part of the Pneumotrac, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
18. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify they are operating normally.
19. The applied part is the flowhead. This along with the SpiroSafe filter, are the contact points for the subject during a spirometry session. There are no adverse effects if the subject comes into contact with any other part of the Pneumotrac device.

14. CE Notice

Marking by the symbol CE 2797 indicates compliance of the Model 6800 Pneumotrac to the Medical Devices Directive of the European Community.

The Pneumotrac is intended for use in a variety of professional healthcare environments, e.g., primary care, hospital wards and occupational health centers, except for near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high. The customer or the user of the Pneumotrac should be assure it is not used in such an environment.

The Model 6800 Pneumotrac has been tested in accordance with:

EN60601-1:2006 + A1:2013 – Medical electrical equipment. General requirements for basic safety and essential performance.

EN 60601-1-2:2015 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

EN 60601-1-2:2015 Emissions tests		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Model 6800 Pneumotrac uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model 6800 Pneumotrac is suitable for use in all establishments, including establishments connected to the public mains network (e.g. at doctor's offices in residential areas).

EN 60601-1-2:2015 Immunity tests		
Immunity test	Test level	Compliance level Reached
Electrostatic discharge (ESD) EN 61000-4-2	Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
Radiated RF EN 61000-4-3	3 V/m 80MHz to 2700MHz	3 V/m 80MHz to 2700MHz
Proximity fields from RF devices EN 61000-4-3	9 to 28 V/m 385 to 5785 MHz As per Table 9 EN60601-1-2:2015	9 to 28 V/m 385 to 5785 MHz As per Table 9 EN60601-1-2:2015

Medical devices may be affected by mobile RF communications equipment including cellular telephones and other personal or household devices not intended for medical facilities. It is recommended that all equipment used near the Pneumotrac comply with the medical electromagnetic compatibility standard and to check before use that no interference is evident or possible. If interference is suspected or possible, switching off the offending device is the normal solution, as is required in aircraft and medical facilities.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided.

15. FDA Notice

Caution: Federal law restricts this device to sale by or on the order of a physician.

16. EU Declaration of Conformity

Product: 6800 Pneumotrac

The manufacturer hereby ensures and declares the above product associated with these instructions for use, is designed and manufactured in accordance with the following QMS regulations and standards.

- European Medical Devices Directive {MDD} 93/42/EEC, as amended.
  This device is classified as IIa per Annex IX of the MDD also meets the provision of the Essential Requirements, Anex I, via compliance with Annex II of the Medical Devices Directive as per Article 11, section 3a, excluding point 4 of Annex II.

- EN ISO 13485 Medical devices. Quality management systems. Requirements for regulatory purposes

Certifying Body: British Standards Institute {BSI}.
BSI Notified Body #: 2797
Certificate Nos. CE 00772, MD 82182

CE
2797

Signed on behalf of Vitalograph (Ireland) Ltd.

Frank Keane.
CEO, Vitalograph Ltd.

17. Guarantee

Subject to the conditions listed below, the manufacturer and its associated companies, (hereinafter called the Company) guarantee to repair or at its option replace any component thereof, which, in the opinion of the Company is faulty or below standard as a result of inferior workmanship or materials.

The conditions of this Guarantee are:

1. This Guarantee shall only apply to hardware defects which are notified to the Company or to its accredited distributor within 2 years of the date of purchase of the equipment, unless otherwise agreed in writing by the Company.
2. Software (meaning computer software, or user installable modules) is guaranteed for 90 days from the date of purchase.

3. The Company warrants the software when correctly used in conjunction with the hardware will perform in the manner described in the Company's literature and user manuals. The Company undertakes to rectify at no expense to the customer any software failure notified with the period stated above, provided the failure can be recreated and the software has been installed and used in accordance with the user manual. Notwithstanding this clause, the software is not warranted to be free of errors.

4. This Guarantee does not cover any faults caused by accident, misuse, neglect, tampering with the equipment, use of consumables items or parts not approved by the Company, or any attempt at adjustment or repair other than by personnel accredited by the Company, nor does it cover reinstatement of any configuration changes caused by the installation of any software.

5. If a defect occurs, please contact the supplier from whom it was purchased for advice. The Company does not authorize any person to create for it any other obligation or liability in connection with Vitalograph equipment.

6. This Guarantee is not transferable and no person, firm or company has any authority to vary the terms or conditions of this guarantee.

7. To the maximum extent of the law, the Company does not accept liability for any consequential damages arising out of the use of, or inability to use any Vitalograph equipment.

8. This Guarantee is offered as an additional benefit to the Consumer's statutory rights and does not affect these rights in any way.

CD-10 Codes for Spirometry

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

Pneumonitis	J67.0-J67.9
Pulmonary, Fibrosis	J84.10
Respiratory conditions due to inhalation of chemicals, gases, fumes and vapors	J68.0-J68.9
Respiratory conditions due to unspecified external agent	J70.9
Sarcoidosis of the Lung	D86.0
Sarcoidosis of the Lung with sarcoidosis of the lymph nodes	D86.2
Bronchiolitis, Acute	J21.0-J21.9
Bronchitis, Not Specified as Acute or Chronic	J40
Bronchospasm, Acute	J98.01
Bronchospasm, Exercised Induced	J45.990
Chronic Bronchitis, Simple	J41.0-J41.8
Chronic Bronchitis, Unspecified	J42
COPD	J44.0-J44.9
Cough	R05
Emphysema	J43.0-J43.9
Other Long Term (Current) Drug Therapy	Z79.899
Shortness of Breath	R06.02
Systemic Sclerosis with lung involvement	M34.81
Contact with and (suspected) exposure to environmental tobacco smoke (acute) (chronic)**	Z77.22
Nicotine Dependence**	F17.200-F17.299

Tobacco Use (NOS)**	Z72.0
Occupational exposure to environmental tobacco smoke**	Z57.31
Personal history of nicotine dependence**	Z87.891
Smoking (tobacco) complicating pregnancy, childbirth, and the puerperium**	O99.330-O99.335
Wheezing	R06.2

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