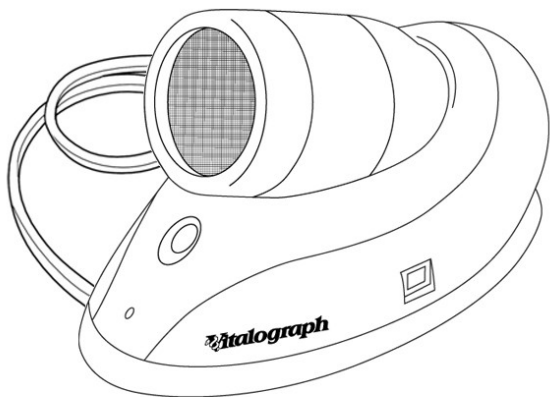


Vitalograph[®]
Pneumotrac
MODEL 6800



Instructions for Use

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1. Main Components of the Vitalograph Pneumotrac

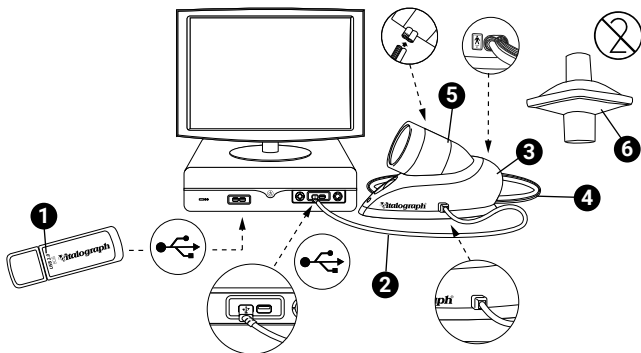


Figure 1 Main components of Pneumotrac

1	USB Flash Drive containing Spirotrac. Reference <i>Spirotrac Instructions For Use</i> for details
2	USB Cable
3	Pneumotrac™ Base
4	Flowhead Connection Tubing
5	Flowhead
6	Bacterial Viral Filter (BVF™)

Note: Computer not supplied

1.1. Features of the Vitalograph Pneumotrac

The features include:

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

2. Setting Up the Vitalograph Pneumotrac

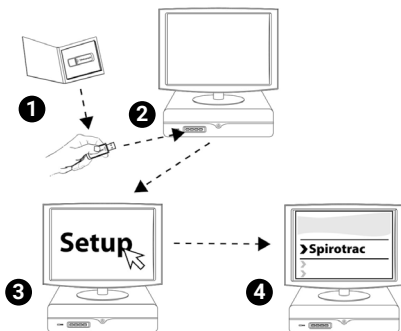



Figure 2

1. Remove Vitalograph® 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 Vitalograph 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 other end of flowhead tubing to the flowhead.
10. Ensure that the ribbed side of the tubing is connected to the ribbed half of the connector. If tubing is connected the wrong way, spirometry results may appear to be inverted (See Figure 1)

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

3. Operating Instructions

The Pneumotrac works with Vitalograph Spirotrac® software. Spirotrac must be installed on the PC to begin testing. Refer to *Spirotrac Instructions 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. Vitalograph intends that a new Bacterial Viral Filter (BVF) be used for every subject to prevent cross contamination. Using a new BVF provides a significant level of protection of the subject, the device and the user against cross contamination during spirometry manoeuvres.

The interior of a Vitalograph flowhead does not require decontamination where a new BVF 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 that the flowhead has become contaminated or where local risk assessment identifies a need for higher level of decontamination, then it should be cleaned as per 'Cleaning and Hygiene' instructions on the Vitalograph website.

5.2. Inspection of the Vitalograph Pneumotrac

A visual inspection is recommended on a routine basis.

1. Remove 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.
2. To remove the flowhead body from the Fleisch element, place the Fleisch element on a hard, flat surface with blue tapping/ribbed connector side of the flowhead body furthest away from the flat surface. Push down on the flowhead body with thumbs and forefingers until it reaches the flat surface. A final pulling and twisting action will separate the parts. To clean the Fleisch element, swill vigorously in warm soapy water. Do not attempt to "rub" or "scrub" at capillaries.

It is recommended that an accuracy check is carried out following cleaning and re-assembly as recommended in the ATS/ERS 2019 guidelines .

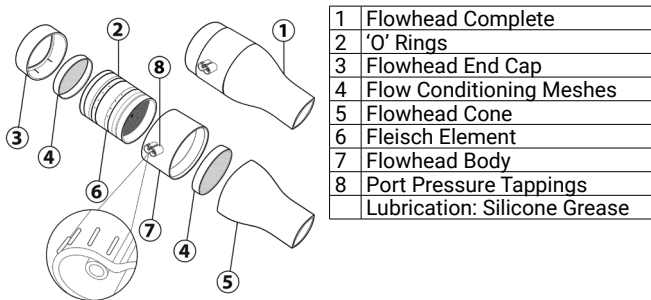


Figure 3: Flowhead Assembly

6. Fault Finding Guide

Problem Fault Symptoms:	<ul style="list-style-type: none"> • Accuracy check variations > +/-3% • False readings suspected
<p>Possible Solutions: (In probable order)</p>	<ul style="list-style-type: none"> • Recheck Accuracy (Section Operating Instructions) • Was the correct syringe volume selected? • Flowhead conditioning mesh missing or blocked. • Flowhead 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:	<ul style="list-style-type: none"> • Test begins automatically • Volume accumulates automatically without the subject blowing. • Very small VC or FVC test displayed
<p>Possible Solutions: (In probable order)</p>	<ul style="list-style-type: none"> • Flowhead and/or tubing not stationary at the start of test. Hold them steady until the 'Ready to Blow' prompt appears. • Restart the test routine.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Rocking Pneumotrac Base
<p>Possible Solutions: (In probable order)</p>	<ul style="list-style-type: none"> • Check for damaged or missing feet. • If any of the feet are damaged or missing replace both feet.
Problem Fault Symptoms:	<ul style="list-style-type: none"> • Reversed or no volume measurements.
<p>Possible Solutions: (In probable order)</p>	<ul style="list-style-type: none"> • 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 Vitalograph. Contact information for approved Vitalograph Service Agents may be found at the start of this manual.

Any serious incident that has occurred in relation to the device should be reported to Vitalograph or its Authorized Representative and the Regulatory Authorities of the country. Refer to the Vitalograph contact information at the start of this manual.

8. Consumables and Accessories
















Cat. No	Description
28350	BVF - Bacterial/Viral Filters (50)
28303	Disposable Noseclips
28501	Eco BVF – Bacterial/Viral Filters (100)
28572	Eco BVF and Disposable Nose Clip (80)
28554	Eco BVF with Bite Lip (75)
28553	Eco BVF with Bite Lip and Disposable Nose Clip (75)
36020	3-L Precision Syringe
42084	Flow Conditioning Mesh (10)
61030	Flowhead Complete
67252	USB Cable
32254SPR	Silicone Grease Pack

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 BVFs constitute minimally soiled waste from human healthcare and should be disposed of in line with local requirements. BVFs are made from polypropylene.

10. Explanation of Symbols

Symbol	Description
	Type BF 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
	Storage Temperature Limit
	Storage Relative Humidity Limits
	Do not re-use
	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 Vitalograph Pneumotrac is a spirometer which measures subject respiratory parameters including but not limited to VC, FVC, FEV₁, 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 paediatrics, 2.5 years and older, in a variety of professional healthcare environments, e.g. primary care, hospitals and occupational health centres.

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	Vitalograph Pneumotrac
Model	6800
Flow Detection Principal	Fleisch type pneumotachograph
Volume Detection	Flow integration sampling @ 100Hz
Volume Accuracy	Within $\pm 2.5\%$
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 $\pm 10\%$
Back pressure	Less than 0.1kPa/L/sec @ 14L/sec
Operating humidity range	30%–75%
Operating temperature range	ISO26782 limits: 17–37°C Design limits: 10–40°C

Performance standards the Vitalograph Pneumotrac meets or exceeds	ATS/ERS 2019, ISO 23747:2007 & ISO 26782:2009
Safety standards	EN ISO 60601:2006
QA/GMP standards	EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282, JPAL, MDSAP
Dimensions	184mm (length) x 106mm (width) x 70mm (height)
Weight	450g
Storage Temperature	0–50°C
Storage Relative Humidity	10%–95%
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 unauthorised changes to the Pneumotrac device may compromise product safety and/or data and as such Vitalograph 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 any 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 that 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 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 as 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 that 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 Vitalograph.
14. Maintenance must not be performed while the device is in use by a subject.
15. Use of accessories and cables other than those specified or provided by Vitalograph 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, or some other persons touching part 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 30 cm (12 inches) to any part of the Pneumotrac, including cables specified by Vitalograph. 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 that they are operating normally.
19. The applied part is the flowhead. This along with the BVF, 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  indicates compliance of the Vitalograph Model 6800 Pneumotrac to the Medical Devices Directive of the European Community.

The Vitalograph Model 6800 Pneumotrac is intended for use in a variety of professional healthcare environments, e.g. primary care, hospital wards and occupational health centres, 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 assure that it is not used in such an environment.

The Model 6800 Pneumotrac has been tested in accordance with:

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

EN 60601-1-2:2007 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 - Emissions tests		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Model 6800 Pneuotrac 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 Pneuotrac is suitable for use in all establishments, including domestic establishments and those connected to the public mains network (e.g. at home and doctor's offices in residential areas)

EN 60601-1-2 - Immunity tests		
Immunity test	Test level	Compliance level Reached
Electrostatic discharge (ESD) EN 61000-4-2	Contact: $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 6 \text{ kV}$ Air: $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 8 \text{ kV}$	Contact: $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 6 \text{ kV}$ Air: $\pm 2 \text{ kV}, \pm 4 \text{ kV}, \pm 8 \text{ kV}$
Radiated RF EN 61000-4-3	3 V/m 80MHz to 2500MHz	3 V/m 80MHz to 2500 MHz

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 Vitalograph product 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 Vitalograph Pneumotrac

Vitalograph hereby ensures and declares that 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 provisions of the Essential Requirements, Annex 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



Signed on behalf of Vitalograph (Ireland) Ltd.

A handwritten signature in black ink, which appears to read 'Frank Keane'.

Frank Keane.

CEO, Vitalograph Ltd.

17. Guarantee

Subject to the conditions listed below, Vitalograph Ltd. 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 1 year 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 that 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 within the period stated above, provided that 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 consumable 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 permitted by 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.

