Pneumotrac
MODEL 6800

Instructions for Use
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1. Main Components of the Vitalograph Pneumotrac

![Figure 1 Pneumotrac Components](image)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>USB Flash Drive containing Spirotrac® Software. Reference Spirotrac Instructions For Use for details</td>
</tr>
<tr>
<td>2</td>
<td>USB Cable</td>
</tr>
<tr>
<td>3</td>
<td>Pneumotrac™ Base</td>
</tr>
<tr>
<td>4</td>
<td>Flowhead Connection Tubing</td>
</tr>
<tr>
<td>5</td>
<td>Flowhead</td>
</tr>
<tr>
<td>6</td>
<td>Bacterial Viral Filter (BVF™)</td>
</tr>
</tbody>
</table>

*Note: Computer not included.*

1.1. Features of the Vitalograph Pneumotrac

- Fleisch type pneumotachograph to measure flow
- Ambient temperature sensor
- USB for power and connection to user computer
- Hygiene drying fan
- Soft pouch to store Pneumotrac
2. Setting Up the Vitalograph Pneumotrac

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 found under User Manual on the installation menu.
5. Close installation and select the Vitalograph Spirotrac icon from the desktop.
6. Install a 9 Volt battery if the hygiene fan is required:
   a. Open battery door underneath the device
   b. Insert battery ensuring that the polarity is correct i.e. + with +.
   c. Close battery door.
7. Connect Pneumotrac to the computer using USB cable (via ports marked with the symbol Figure 1).
8. Connect one end of 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)
11. Take one flowhead filter from its packaging and place in the flowhead holder on the Pneumotrac base.

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

1. 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
2. For hygiene purposes, it is recommended that the flowhead is docked between testing subjects so that the small suction fan in the docking station can remove all traces of moisture from the breathing circuit of the flowhead. The fan will activate for approximately 30 seconds. Spirotrac controls the fan.

4. **Power Management**
   1. Pneumotrac is powered over USB.
   2. Pneumotrac may be safely powered down by disconnecting the USB cable from the device.
   3. A 9 Volt battery is required for the hygiene fan.

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\(^1\).

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1 Derived from terminology and guidance taken from ATS/ERS Standardisation 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 > +/-3%  
| • 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.  
| | • Flowhead pressure tapping holes blocked.  
| | • Fleisch element assembly sealing 'O' rings damaged.  
| | • 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 test. Hold them steady until the ‘Ready to Blow’ prompt appears.  
| | • Return to Main Menu and re-enter the test routine. |

Figure 3: Flowhead Assembly
### 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 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

<table>
<thead>
<tr>
<th>Cat. No</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>28350</td>
<td>BVF - Bacterial/Viral Filters (50)</td>
</tr>
<tr>
<td>20303</td>
<td>Disposable Noseclips</td>
</tr>
<tr>
<td>28501</td>
<td>Eco BVF – Bacterial/Viral Filters (100)</td>
</tr>
<tr>
<td>28572</td>
<td>Eco BVF and Disposable Nose Clip (80)</td>
</tr>
<tr>
<td>28554</td>
<td>Eco BVF with Bite Lip (75)</td>
</tr>
<tr>
<td>28553</td>
<td>Eco BVF with Bite Lip and Disposable Nose Clip (75)</td>
</tr>
<tr>
<td>36020</td>
<td>3-L Precision Syringe</td>
</tr>
<tr>
<td>42084</td>
<td>Flow Conditioning Mesh (10)</td>
</tr>
<tr>
<td>61030</td>
<td>Flowhead Complete</td>
</tr>
<tr>
<td>67252</td>
<td>USB Cable</td>
</tr>
<tr>
<td>32254SPR</td>
<td>Silicone Grease Pack</td>
</tr>
<tr>
<td>76050</td>
<td>Filters (50) and Tweezers</td>
</tr>
</tbody>
</table>
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. Please note that batteries must be disposed of separately according to the regulations for your country.

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Type BF equipment" /></td>
<td>Type BF equipment</td>
</tr>
<tr>
<td><img src="image" alt="Class II" /></td>
<td>Class II</td>
</tr>
<tr>
<td><img src="image" alt="VA" /></td>
<td>Power rating</td>
</tr>
<tr>
<td><img src="image" alt="Direct current" /></td>
<td>Direct current</td>
</tr>
<tr>
<td><img src="image" alt="Instructions for Use; operating instructions" /></td>
<td>Instructions for Use; operating instructions</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Year of Manufacture (Date format YYYY-MM-DD)" /></td>
<td>Year of Manufacture (Date format YYYY-MM-DD)</td>
</tr>
<tr>
<td><img src="image" alt="USB connector" /></td>
<td>USB connector</td>
</tr>
<tr>
<td><img src="image" alt="The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste" /></td>
<td>The device must be taken to separate collection at the product end-of-life. Do not dispose of these products as unsorted municipal waste</td>
</tr>
<tr>
<td><img src="image" alt="Fragile, handle with care" /></td>
<td>Fragile, handle with care</td>
</tr>
<tr>
<td><img src="image" alt="Keep Dry" /></td>
<td>Keep Dry</td>
</tr>
</tbody>
</table>
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, FEV\textsubscript{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 Spirotac 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

<table>
<thead>
<tr>
<th>Product</th>
<th>Vitalograph Pneumotrac</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>6800</td>
</tr>
<tr>
<td>Flow Detection Principal</td>
<td>Fleisch type pneumotachograph</td>
</tr>
<tr>
<td>Volume Detection</td>
<td>Flow integration sampling @100Hz</td>
</tr>
<tr>
<td>Volume Accuracy</td>
<td>within ±2.5%</td>
</tr>
</tbody>
</table>
## 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 0.1kPa/L/second @14L/s

## Operating temperature range
ISO26782 limits: 17–37°C
Design limits: 10–40°C

## Performance standards the Vitalograph Pneumotrac meets or exceeds

## Safety standards

## EMC standards
60601-1-2: 2001 Medical

## QA/GMP standards
EN ISO 13485, FDA 21 CFR 820, CMDR SOR/98-282 & JPAL

## Dimensions
170mm (length) x163mm (width) x 45mm (height)

## Weight
345g

## 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.

20. 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.

21. 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.

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

14. CE Notice
Not applicable.

15. FDA Notice

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

16. EU Declaration of Conformity
Not applicable.
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.