

Vitalograph®

Your cardio-respiratory partner



Data you can rely on.
People you can trust.

Vitalograph Products & Services Guide

Vitalograph® is a world leading provider of outstanding quality cardio-respiratory devices, clinical trial services and medical equipment servicing. With a pioneering heritage of excellence spanning half a century we continue to make valuable contributions to effective medical care and enhanced quality of life.

Vitalograph have been pioneers since our earliest days when we first made it possible to take spirometry out of laboratories and bring it into GPs surgeries. Our continuous investment in product development reflects our pioneering spirit and demonstrates our commitment to supporting respiratory professionals and those they care for.



Managing Director, Vitalograph Ltd.

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Vitalograph Spirotrac

Cardio-respiratory diagnostic software

Spirotrac® cardio-respiratory diagnostic software integrates high quality spirometry, pulse oximetry, 12-lead ECG, COPD assessment, blood pressure measurement, challenge testing and more in a simple, flexible solution.

- Network multiple Spirotrac cardio-respiratory diagnostic software devices in their own network or to a central database on your existing networks
- High quality spirometry using Fleisch pneumotachograph
- Bronchial Challenge Testing (Methacholine and Mannitol)
- 6 Minute Walk Test and COPD Assessment
- Pulse Oximetry USB
- Blood Pressure USB
- Weighing Scale Bluetooth
- 12-lead ECG Bluetooth



Order Number: 70200

Spirometry software

Vitalograph Spirotrac Software with Pneumotrac

Highly accurate PC based spirometry solution

Combines the power of your Windows® PC with Vitalograph measuring technology for early detection of respiratory disease and integration with your institution network.

- Accurate, robust and linear Fleisch pneumotachograph
- Intuitive user interface with workflow orientated presentation
- Automatic FEV₁ trend chart of actual and normal range data as subject is selected
- Open session, f/v and v/t curves, all test data and test quality in one view
- Automatic storage of all test data and events, including calibration log
- Built-in test quality checks
- Choice of exciting incentives
- Fully scalable database capacity using powerful Microsoft® SQL server technology
- Network ready



Order Number: 77000

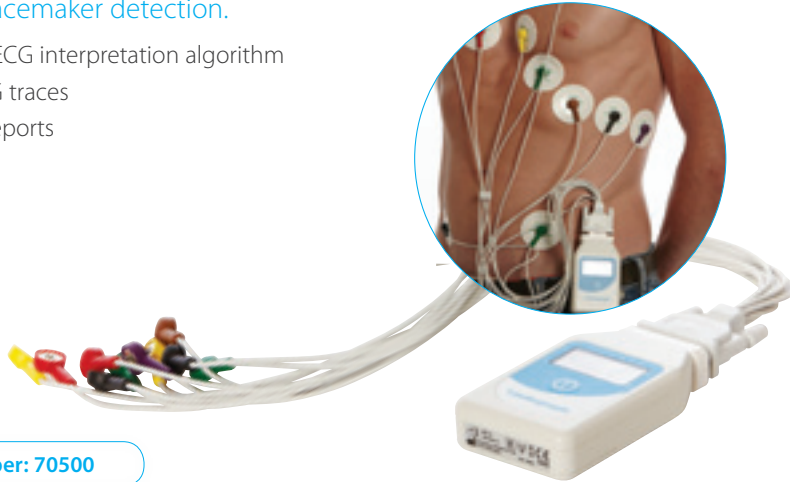
Spirometry software

Vitalograph Spirotrac PC Based ECG

Power and sophistication made simple

The Vitalograph ECG device software is elegantly integrated into Spirotrac allowing for the capture of 12-lead electrocardiography. Fast, safe, wireless transmission allows ECG data to be captured, displayed, stored, analysed and interpreted with minimal lead artefact from movement or electrical sources. ECG tracings are captured and displayed in real-time and data can be saved for recall, reporting and printing. The built-in display also provides information on electrode contact problems, heart rate, battery status, communication status and digital pacemaker detection.

- Integrated ECG interpretation algorithm
- 12-lead ECG traces
- Choice of reports



Order Number: 70500

ECG hardware and software

Vitalograph In2itive

For high quality spirometry on the move

Vitalograph In2itive™ combines the benefits of full spirometry, data integration and mobility in a small lightweight handheld spirometer.

- Features Fleisch flow measuring technology and simple icon driven menu
- Storage for 10,000 subjects
- Subject data from Spirotrac may be downloaded automatically – saving time and eliminating data entry errors
- Session can be automatically transferred to, and synchronised with, Spirotrac
- Colour touch screen
- Battery life for a full day of off-site testing
- Over 50 test parameters
- Choice of child incentives with sound effects
- Remote flowhead option enables the subject to view incentives while performing the test
- Print via your PC (Spirotrac or Vitalograph Reports) or print direct to USB printer (using optional print cradle)

Order Number: 79000 In2itive and Spirotrac Software,
79400 In2itive and Reports Utility

High quality spirometers



Vitalograph micro

Low cost spirometry made simple

Reliable, affordable spirometry testing is easier than ever with the new Vitalograph micro™. This compact, lightweight, handheld spirometer is not only great value but it is packed with a host of features including full colour touch screen, icon driven menu and highly accurate and robust flow sensor technology.

- Supplied with Vitalograph Reports Software
- Configurable PDF reports for archiving or printing
- Full colour touch screen
- Clear sounds for audio feedback
- Real-time test quality prompts
- Flow/Volume and Volume/Time curves in real time
- Expandable graph views for full visualisation
- Display overlay of 3 best blows, best test and LLN
- Simple icon driven menu for ease of use
- Choice of over 40 parameters
- Pre and post bronchodilator testing options
- Predicted sets including ERS, NHANES & GLI
- Removable flowhead for easy cleaning



Order Number: 63310

High quality spirometers

Vitalograph COMPACT

Cardio-respiratory diagnostic workstation

The Vitalograph COMPACT™ Expert is a medical workstation that integrates high quality spirometry, pulse oximetry, 12-lead ECG, COPD assessment, blood pressure measurement, challenge testing and more in a flexible, integrated solution.

- Networking multiple COMPACT devices in their own network or to a central database on your existing networks
- High quality spirometry using Fleisch pneumotachograph
- Bronchial Challenge Testing (Methacholine and Mannitol)
- 6 Minute Walk Test and COPD Assessment
- Weighing Scale Bluetooth
- 12-lead ECG Bluetooth
- Pulse Oximetry USB



Order Number: 67800

High quality spirometers

Vitalograph Alpha Touch

For precision spirometry, portability, printing and PC connectivity

Simple touch screen spirometry with in-built printing and automatic PC connectivity.

- Fleisch pneumotachograph, the best performing flow measuring technology in the world
- Automatic two-way synchronisation of patient data and test sessions between ALPHA Touch and Spirotrac
- Simple icon driven menu with large, high resolution colour touch-screen
- Storage capacity for 10,000 subjects
- Over 50 test parameters
- % predicted or SDS scores comparison
- F/V and V/T curves viewable in real time
- Pre-post bronchodilator comparison
- Single or multi-breath
- Hours of battery life
- Choice of exciting incentives

Order Number: 65500



High quality spirometers

Vitalograph ALPHA

Effective spirometry – pure and simple

The Vitalograph ALPHA™ is a dedicated all in one desktop spirometer featuring the proven Vitalograph Fleisch pneumotachograph to provide unparalleled accuracy and outstanding performance.




- Measures VC, FVC, FEV₁, FEV₁ Ratio, PEF, FEF_{25-75%} and more
- On-screen visualisation of volume/time and flow/volume curves
- Links to PC, via USB, with Vitalograph Reports Software
- Saves multiple pre-tests for subsequent post-testing
- Compact flash card backup/storage
- Information presented in easy to read format
- Fast, silent printer that prints up to 140 tests per roll
- Battery and mains power with integrated battery for off site testing
- Real time clock
- Autoclaveable flowhead
- Facility for user accuracy checks

Order Number: 65000



High quality spirometers

Spirometer Selection Guide

	Desktop			Handheld				PC-Based			Medical Workstation	
												
	ALPHA	ALPHA Touch	ALPHA Touch with Spirotrac	Micro	In2itive	In2itive with Spirotrac	In2itive with Reports	Spirotrac with Pneumotrac™	Spirotrac with Pneumotrac & 12 Lead ECG	Spirotrac with other devices	COMPACT with Pneumotrac	COMPACT with Pneumotrac & 12 Lead ECG
VC Testing	●	●	●		●	●	●	●	●	●	●	●
FVC Testing	●	●	●	●	●	●	●	●	●	●	●	●
Post BD Testing	●	●	●		●	●	●	●	●	●	●	●
Predicted Values	●	●	●	●	●	●	●	●	●	●	●	●
Indices (Parameters)	8+	50+	60	8	50+	60	50+	60	60	60	60	60
Interpretation	●	●	●		●	●	●	●	●	●	●	●
Quality Prompts	●	●	●		●	●	●	●	●	●	●	●
Incentives		●	●		●	●	●	●	●	●	●	●
Internal Printer	●	●	●									
PDF Reports	●	●	●	●	●	●	●	●	●	●	●	●
Internal Battery	●	●	●	●	●	●	●					
Touch Screen		●	●		●	●	●				●	●
dB in device		●	●		●	●	●				●	●
EMR/HIS Connectivity			●			●		●	●	●	●	●
Colour display	●	●	●		●	●	●	●	●	●	●	●
Data Export	●	●	●		●	●	●	●	●	●	●	●
Challenge Test		●	●			●		●	●	●	●	●
Pulse Oximetry			●			●		●	●	●	●	●
6MWT / COPD Assess			●			●		●	●	●	●	●
Blood Pressure			●			●		●	●	●	●	●
Medical Scales			●			●		●	●	●	●	●
Resting 12-lead ECG			●			●		●	●	●		●

Vitalograph AIM

Effective inhaler training on dry powder and metered dose inhalers

The unique Vitalograph AIM™ (Aerosol Inhalation Monitor) is designed to assist in training subjects to use their inhaler correctly. Mastery of the correct technique will support more accurate drug delivery and good patient compliance, resulting in better disease management and fewer visits to medical professionals.

- Validates effective use of an inhaler
- Objective identification of proper use of the inhaler device
- Identifies correct choice of inhaler device type
- Identifies and quantifies poor inhaler technique
- Assists in training patients to use their inhaler correctly
- Provides clear feedback and instructions to subject and trainer
- Easy to use, hygienic and low cost
- Can optionally be used with a spacer



Order Number: 45710

Inhaler training





Cardio-Respiratory Clinical Trials Services

As a global provider of cardio-respiratory related services Vitalograph has undertaken multi-centre clinical trials for many of the world's foremost pharmaceutical companies, biotech and CROs. With a 50 year heritage of service in the respiratory field, and through our dedicated and motivated team of professionals, we bring the same commitment to excellence to all our clinical trials services. Our wide range of services includes:

- Protocol design consultation
- Expert review of centralised cardiac and respiratory data
- Centralised global data services
- e-Diaries, spirometry, ECG, FeNO, pulse oximetry and more
- Project, logistics and data management
- Customisation of software, devices and manuals to match your protocol
- Custom reports and study materials accessible via web portals
- Onsite and remote training of monitors and investigators
- Global 24/7 technical support



Our rigorous systems and processes

Within an audited ICH-GCP environment we have developed a wide range of sophisticated systems and processes to protect the security and success of your trial including:

- Robust disaster recovery system with multiple fail over sites ensuring that your data is always available and secure
- Automatic data backup in site medical devices and software – ensuring no data loss
- Encrypted internet data transmission system – highly secure, fast and cost effective via local Internet Service Providers
- Web-based access to data, e-diary results and reports – a powerful tool for monitoring the progress of your study using Vitalograph's web based technologies

Our project management

Our project management expertise ensures that studies run to specification and schedule while ensuring that all steps involved in successful completion are conducted in a timely way with ongoing analysis and management of risks to GCP. Each study is assigned a dedicated Project Manager with many years experience in respiratory clinical trials. Project Managers ensure that the following activities are tailored to suit the needs of each study:

- Study management of the cardio-respiratory data collection including liaison with, and reporting to, sites, monitors and sponsor teams
- Spirometry consultation including protocol enhancements, customisation specifications and user acceptance testing
- Centralised Data Management with QA review service and provision of data sets to sponsors, CROs and EDC companies

Cardio-Respiratory Training for Sponsors

Vitalograph provide a unique and customised respiratory training day for Clinical Trials. Specifically targeted at pharmaceutical companies and CRO's the training day aims to educate study teams to the modern respiratory clinical trial:

- Includes an overview of the different methods of collecting respiratory data such as spirometry, pulmonary function testing and body plethysmography
- Common respiratory diseases and related key parameters
- Endpoint selection
- Home data capture
- Overview of spirometry
- Technical review of spirometry data
- Hands on experience with Vitalograph equipment



Cardio-Respiratory Over-Reading Services

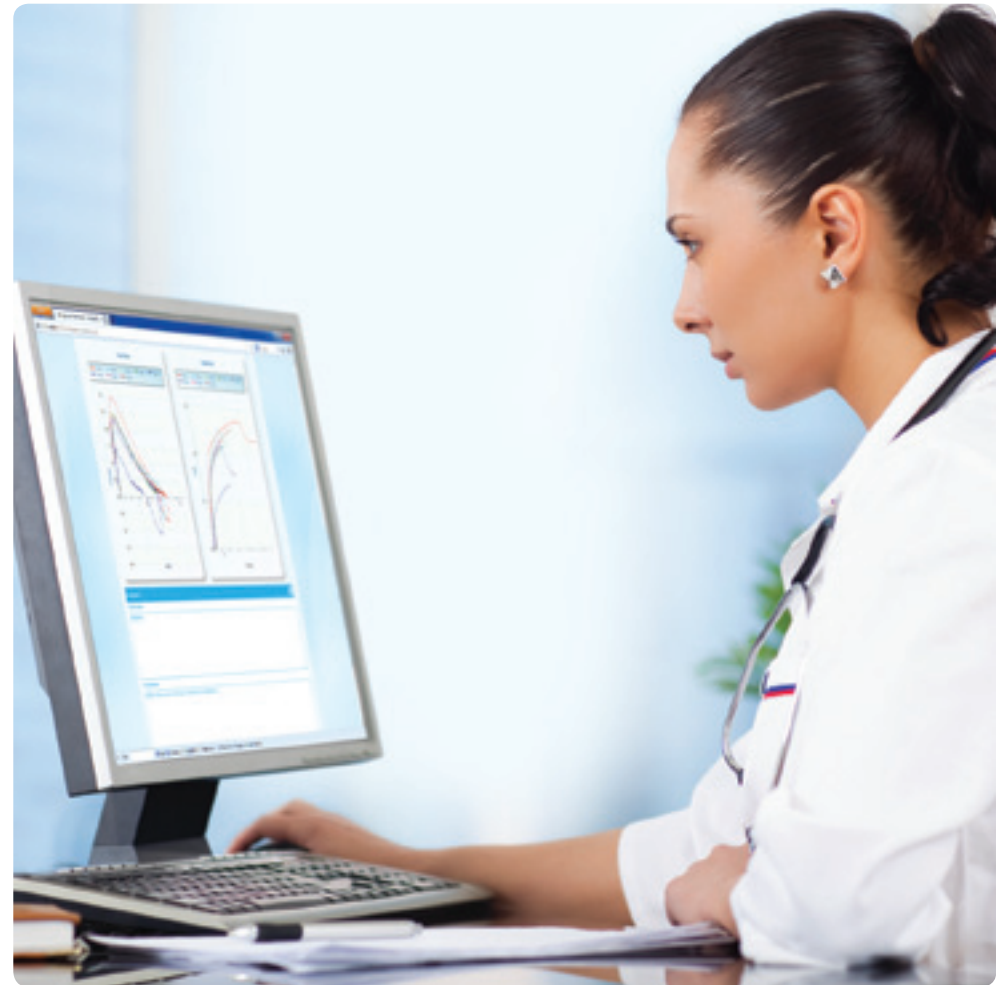
Vitalograph employs expert pulmonary physiologists to provide quality assurance review of respiratory test data and cardiologists to review cardiac safety monitoring in respiratory studies. Our sophisticated over-read system enables prompt identification of shortfalls in pulmonary function and cardiac testing quality arising from poor test acceptability or inappropriate use of test protocols or training issues.

- Technical review spirometry data to ensure ATS/ERS 2005 criteria have been met and maintain high data quality
- Maximum 72 hour turnaround time for spirometry technical review with most feedback returned within 24 hours
- Technical review has been shown to reduce the number of rejected spirometry sessions in a respiratory clinical trial

Spirotrac Software Customisation Services

Vitalograph uses in-house specialists to design and deliver study specific software solutions that meet the needs of individual sponsors to medical device software standards.

- Fully customisable spirometry, ECG and e-Diary solutions
- Easy to use software meeting the technical requirements of 21 CFR-Part 11
- Customised workflow to ensure that testing order and visit schedule is maintained
- Customised alerts to monitor protocol specific inclusion, exclusion and safety criteria
- Alerts reports can be generated to allow efficient monitoring by the study team
- Full integration with other Vitalograph solutions



Medical Device Solutions for Clinical Trials

Vitalograph COMPACT

The COMPACT Expert is a fully validated class II medical device which seamlessly integrates a wide range of medical testing options. These options include:

- As a dedicated medical device/workstation the unit is "locked down" for its designed use only
- Spirometry, FeNO, 12-lead ECG, holter monitor, SpO2, BP, e-Diary and challenge testing
- COMPACT Expert allows collection of multiple end point parameters in a single integrated device
- Provides security and audit trail features in line with the technical requirements of 21 CFR Part 11
- Ideally suited to patient home monitoring

Vitalograph In2itive

The In2itive e-diary is designed to interact directly with the COMPACT Expert to download data at site or dock with our GSM modem cradle to transmit data using the mobile phone network.

- Class II (US) and IIa (Europe) medical device certification ensures that the software, hardware and data transmission technologies comply with the current industry and regulatory standards

We are able to customise these devices to meet the needs and requirements of your protocol ensuring better device compliance in a single integrated unit.

Vitalograph In2itive e-Diary

Integrated flowhead

The pioneering In2itive™ e-Diary combines an integrated diagnostic spirometer, featuring a removable flow head, with a high resolution colour touch screen.

- Secure data transfer from the study centre or transmitted directly from the subject's home for immediate population of centralised study database
- Able to transmit over mobile phone network
- All data can be viewed using our web based technologies
- Records symptoms, medication use, patient reported outcomes and quality of life questions for any therapeutic area
- On-screen quality feedback
- Diagnostic spirometry accuracy
- Can be configured to meet the objectives and endpoints

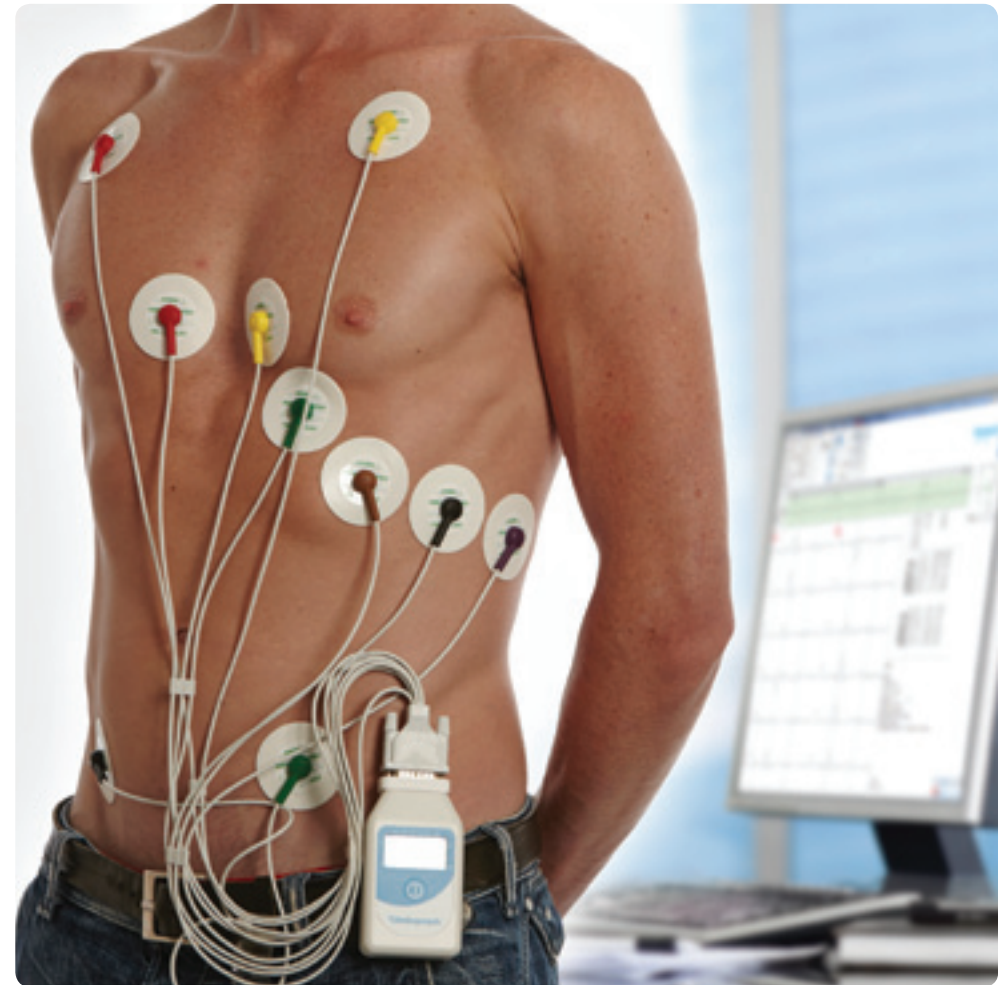


Order Number: 79600

Clinical trials

Spirometry, ECG, BP, Weight, SpO2, FeNO, Questionnaires and ePRO in Clinical Trials

- ▶ Ability to electronically capture static blood pressure, SpO2, FeNO and holter data electronically, eliminating the potential for transcription errors
- ▶ All data is fully audit trailed and captured in a 21-CFR Part 11 environment
- ▶ Each technology is seamlessly integrated into Vitalograph's Spirotrac software allowing for the quick and efficient switching between measurement devices
- ▶ Reduced footprint at site as all data is captured through one central device
- ▶ Captured using a validated medical device.



Vitalograph copd-6

COPD screening monitors available in Standard/USB/Serial/Bluetooth

The Vitalograph copd-6™ is an accurate and cost effective 'case selection' or 'screening' device that identifies potential cases of COPD.

- For the early detection of COPD - quickly, simply and accurately
- Identifies those at risk of COPD at the pre-symptomatic stage
- Screens out those who do not have COPD
- Monitors COPD patients using their 'number', the obstructive index – FEV₁ as a percent of predicted
- Displays FEV₁, FEV₆, ratio and % predicted, obstructive index, COPD classification and lung age
- Built-in quality of blow indicator on a large, easy to read display
- Easy to clean flowhead
- Can be used with hygienic SafeTway mouthpieces or a BVF
- Lung Age meter also available



Order Number: 40200 Standard

Screening for COPD

Vitalograph asma-1

Electronic asthma monitors available in Child/Standard/USB/Serial/Bluetooth

The Vitalograph asma-1™ is an easy to use, yet sophisticated, electronic asthma monitor that makes the monitoring of asthma simpler and more accurate than ever before. By measuring FEV₁, as well as peak flow, the asma-1 gives a clear picture of lung health. The asma-1 stores up to 600 test sessions and automatically assesses test quality.

- Measures FEV₁ and PEF
- Child version measures PEF, FEV₁, FEV_{0.5} and FEV_{0.75}
- Simple to use
- Large, easy to read display
- No need for record cards
- Quality of blow indicator
- Suitable for multi-subject use with standard size SafeTway mouthpieces
- Uses long life AAA batteries
- Variants with communications capability available



Order Number: 40000 Standard

Monitoring asthmatics

Vitalograph lung monitor

Home lung function monitors available in Standard/USB/Serial/Bluetooth

This easy to use home monitoring device is designed to record key lung function parameters for those with respiratory conditions including cystic fibrosis and transplant patients.

- Suitable for multi-subject use in clinic with SafeTway mouthpieces
- Automatically stores best values in a test session
- Variants with communications capability available
- Simple to use with a large, easy to read display
- Electronic record – no need for record cards
- Stores 200 test sessions
- Measures FEV₁, FEV₆ and the ratio
- Displays % of personal best FEV₁
- Quality of blow indicator
- Easy to clean flowhead
- Uses long life AAA batteries
- Meets ATS/ERS:2005 Spirometry Guidelines



Order Number: 40550 Standard

Monitoring cystic fibrosis and transplant patients

Vitalograph 4000 Series Selection Guide

	Variant	PEF	FEV ₁	FEV ₆	FEV ₁ Ratio	FEV _{25-75%}	FEV _{25-75%} %	Lung Age	Memory	Personal Best	GOLD	PDF Reports	SpV Reports
	asma-1™ standard	●	●	○	○	○	○	○	600	●	○	○	○
	asma-1 child version	●	●	○	○	○	●	○	600	●	○	○	○
	asma-1 usb/s/bt	●	●	○	○	○	○	○	600	●	○	●	●
	copd-6™ standard	○	●	●	●	○	○	●	○	○	●	○	○
	copd-6 usb/s/bt	○	●	●	●	○	○	●	○	○	●	●	○
	lung monitor standard	○	●	●	●	○	○	○	200	●	○	○	○
	lung monitor usb/s/bt	○	●	●	●	○	○	○	200	●	○	●	○
	lung age standard	○	●	○	○	○	○	●	○	○	○	○	○

Developer's Kits are available and include USB, Serial and Bluetooth comms devices, dongle, cables, Vitalograph Reports Software, device API, software code and access to the R&D Technical Support Hotline.

● Available / ○ Not Available

Peak Flow Meter asmaPLAN

The simple, accurate way to monitor asthma

- Accurate
- Compact, lightweight and portable
- Robust and hard-wearing
- Features comfortable integral mouthpiece
- Easily read scale marker labels
- Conforms to peak flow standards including EN ISO 23747:2007
- Suitable for adults and children
- Suitable for multi-subject use with SafeTway mouthpieces



Order Number: 43600

Monitoring asthmatics

Vitalograph myPEF

Web enabled Peak Flow Meter

Vitalograph Peak Flow Meters conform to all peak flow standards including ISO 23747:2007

- Web enabled asthma monitoring
- Secure, personal, online PEF record
- Accurate, robust and pocketable
- Integral protective cover
- World's thinnest PFM
- Longest scale
- Patented dual zone markers
- Suitable for adults and children



Order Number: 43950

Monitoring asthmatics

Syringes and Consumables

Vitalograph's wide range of respiratory consumables, which are designed to fit most respiratory devices, offer exceptional protection against cross infection, support effective spirometry and represent great value for money.

Vitalograph Precision Syringe

- 3-L Precision Syringe

Order Number: 36020

- 1-L Precision Syringe

Order Number: 20408



SafeTway® Mouthpieces

- SafeTway mouthpieces (200)

Order Number: 20242

- SafeTway mouthpieces mini (50)

Order Number: 20980

- Disposable Inhaler SafeTway (180)

Order Number: 29770



BVF™ Bacterial/Viral Filters

Single use filters for effective filtration of bacteria, viruses and expectorated matter. Suitable for inspiratory and expiratory spirometry testing.

Order no.	Colour:	To fit spirometers from:
28350	Blue (Small Mouthpiece)	Most office spirometers including Vitalograph, MIR and Micro Medical
28362	White	Most Lab PF Equipment, including Sensormedics, PK Morgan, Ganshorn (new)
28363	Clear	Jaeger/VIASYS/Carefusion PF Lab Equipment
28365	Light Blue	MedGraphics PF Lab Equipment
28383	White Translucent	Chest, Fukuda, Minato
28368	Green	Ferraris/nSpire/PDS/KoKo
28401	Translucent	Medisoft PFT equipment and most office spirometers including Vitalograph, Cosmed, MIR, Carefusion (Micro Medical)

Pulmonary Function Test Kit Examples

Some of the available Pulmonary Function Test Kits:

- PFT Kit White BVF Silicone (50)

Order Number: 28381

- PFT Kit Clear BVF Silicone (50)

Order Number: 28382

Bite-On Mouthpieces

Fits all BVF filters except blue Cat No. 28350

- Rear Bite-on Mouthpiece Silicone (50)

Order Number: 20310

- Front Bite-on Mouthpiece Silicone (50)

Order Number: 20926

- Disposable Oval Mouthpiece (50)

Order Number: 20989

Disposable Noseclips

- Disposable Noseclips (200)

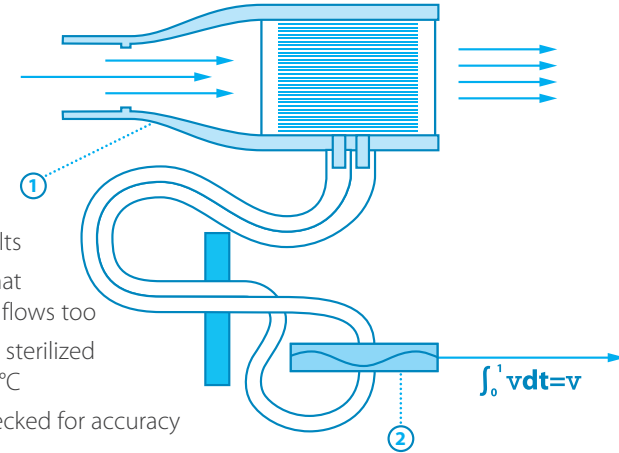
Order Number: 20303



Vitalograph Fleisch Flow Technology

The measuring technology used by Vitalograph in diagnostic spirometer devices is the Fleisch pneumotachograph which makes an accurate, robust, linear and reliable flow measurement spirometer. Extremely low flow impedance ensures that even with a BVF in the measuring system, the system flow impedance is well below the requirements of the current spirometer standard ISO26782:2009. The advantage of this technology makes these devices:

- Easy to use
- Extremely robust
- Has no moving parts
- Accurate
- Provides low back pressure, even with BVF (within ERS/ATS standard)
- Reliable with consistent results
- Uses linear flows meaning that accuracy applies to very low flows too
- Easily cleaned, disinfected or sterilized including autoclaving at 137°C
- Can be easily and simply checked for accuracy
- Can be easily calibrated if necessary
- Meets ISO 26782:2009 and ATS/ERS:2005 spirometry standards





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