

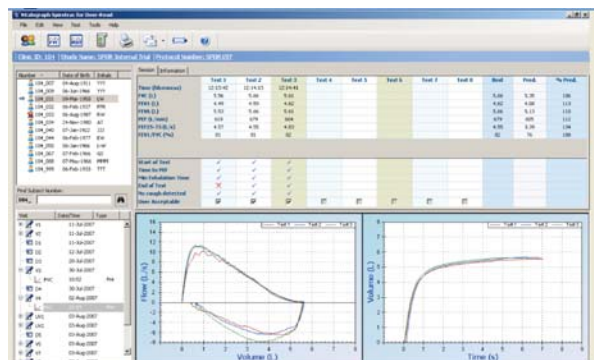
the difference is clear

Spirotrac[®] Centralized Pulmonary Function Testing

Revolutionary delivery of assured quality for respiratory studies

- ❖ Designed for speed and ease of use with study work flow visualization
- ❖ Fleisch pneumotachograph with integrated temperature sensor maintains high accuracy throughout the day
- ❖ On-screen QA messages after each test to guide the technician
- ❖ All tests are saved, whether good or bad
- ❖ Mandatory daily accuracy check
- ❖ One click automatically transmits encrypted data to the Vitalograph data management centre
- ❖ 24-48 hour expert QA review by Vitalograph for acceptability and repeatability with feedback to study sites to maximize data quality
- ❖ Standardized with Vitalograph 6800 Pneumotracs[™] at all sites or Web data capture from sites' existing specialist instrumentation (e.g. DLco & FRC)
- ❖ Timely, quality data ready for analysis – fast data lock
- ❖ Spirotrac[®] integrated application with the Vitalograph PEF/FEV₁ Diary
- ❖ Regular reports with on-line access via the VIEWER[™] web portal
- ❖ GCP, FDA 21CFR Part 11 and HIPAA compliant
- ❖ Optional biometric logon for technician (no need to remember password) and for subject id confirmation for error-free testing
- ❖ Integrated challenge test system

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



As a global provider of respiratory related services Vitalograph has undertaken clinical trials for many of the world's foremost pharmaceutical companies, biotechs and CROs.

With a 50 year heritage of service in the respiratory field, and through our experienced team of professionals, we bring an enduring commitment to excellence to all our clinical trial services.

These services include:

- Project management
- Data management
- Protocol review
- Customization of software and manuals
- Custom reports
- Web portals
- Site visits
- Global 24/7 support in multiple languages
- Shipping, installation and training at sites
- Translations
- Training at investigator and monitor meetings plus specialist training as required
- QA review and Data Management
- Integration to e-CRF systems optional
- Dedicated secure study servers with remote mirror servers for live back-ups.

Vitalograph specialises in respiratory clinical trials requiring electronic data capture (EDC).

Where EDC is not required we offer a range of respiratory diagnostic devices to suit every application including PC based spirometry systems, hand-held storage spirometers or desktop spirometers with data storage or paper records for manual entry into CRFs.

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Quality control of respiratory measurements in global trials

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