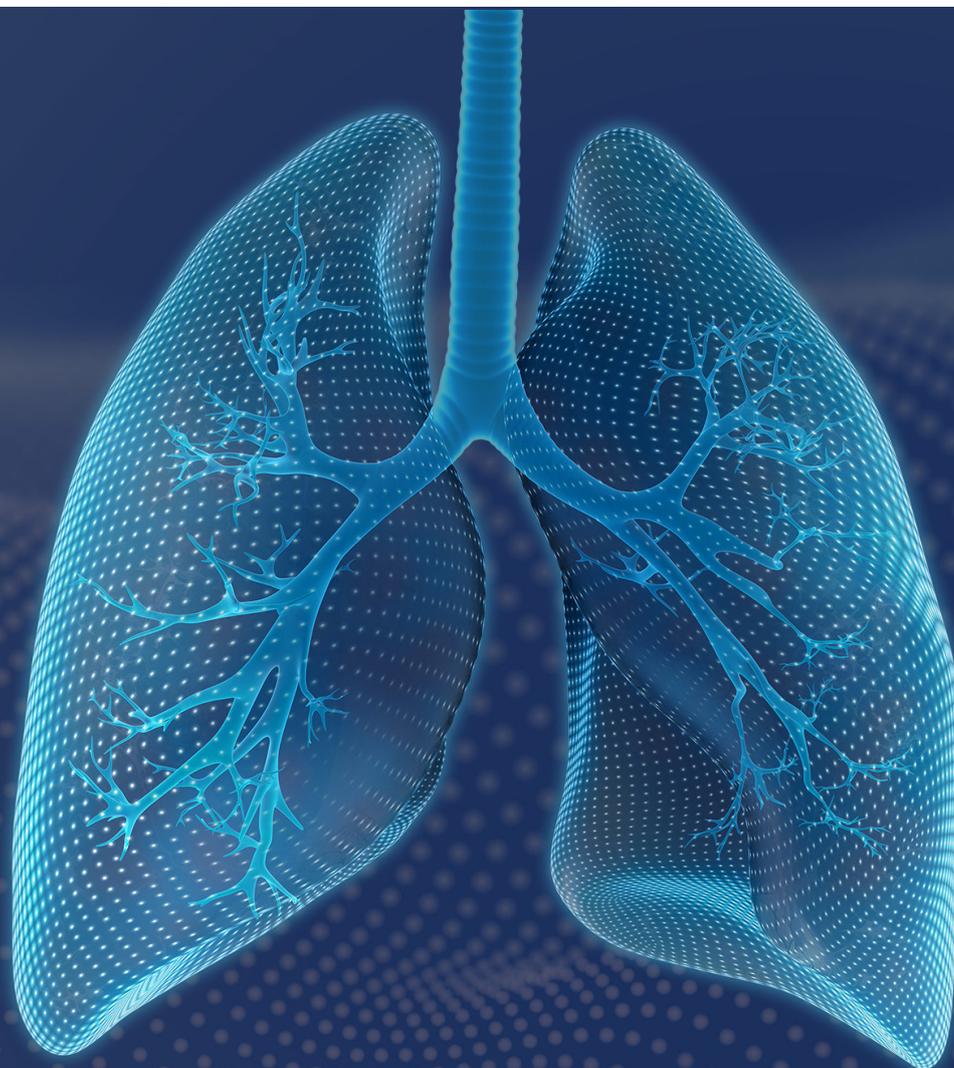


Clinical Trials

CLINICAL TRIALS SOLUTIONS

A trusted partner to meet your clinical study needs



A Global Leader in Respiratory Diagnostics

 **Vitalograph**[®]

vitalograph.com

Vitalograph Clinical Trials Solutions

Vitalograph offers tailored solutions and a personalized service to meet a wide range of respiratory clinical study needs.

We specialize in adapting our solutions to deliver accurate and reliable respiratory end-point data for your trial.

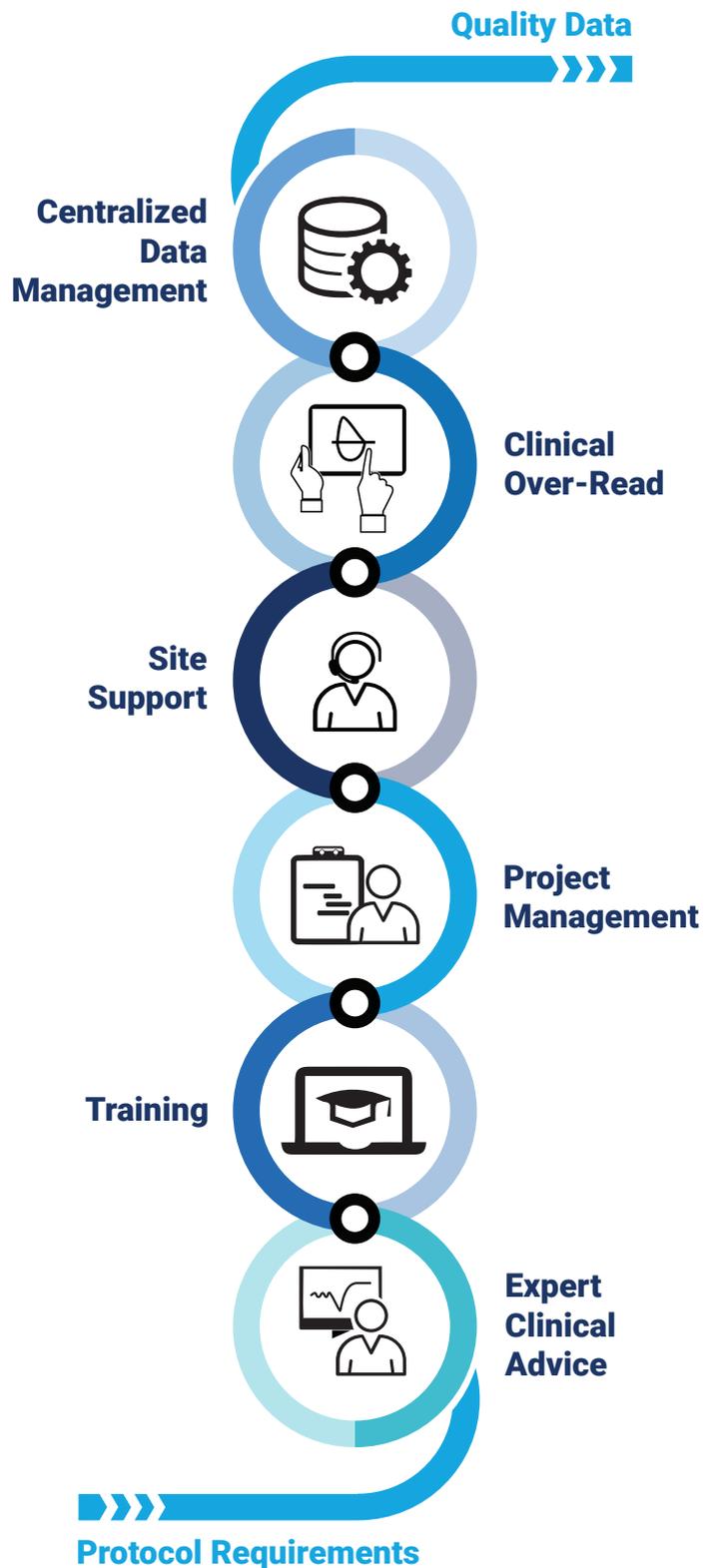
Our solutions are based on the requirements of your clinical operations team, designed to gather the best quality data with the most appropriate systems.

As a trusted partner of many biotech and pharmaceutical companies, we specialize in respiratory studies: local to global, single to multiple end-points, in clinic to home and remote monitoring.

Vitalograph® will be there to provide expertise and guidance through every step of the process, to ensure accurate, timely delivery of trial end points.

Our approach to study design is flexible and our team is easily contactable, ready to listen and willing to do what is needed to ensure the smooth progression of your study.

We are committed to creating long term partnerships with our clients through our experienced and responsive teams. When you partner with Vitalograph you have direct access to our team of knowledgeable project and data managers, clinical respiratory physiologists, cough analysts, software development engineers, QA and logistic specialists, and highly experienced site support capabilities.



Our Services



Centralized Data Management

Collecting and collating the highest quality data for your study.

Our Data Management Service Team provide a dataset incorporating centralized data collected from integrated platforms. Datasets are defined by the protocol requirements and detailed discussion with sponsor data teams. We will provide recommendations informed by our broad experience of data management including suggestions for reports which can be customized if required.

We employ a range of tools to provide secure and reliable ongoing reports on the status of your study data with flexible delivery options, including real-time, user-generated, or scheduled according to the needs of the sponsor team.

Vitalograph's data management services offer data integrity, accuracy and security with flexible outputs including:

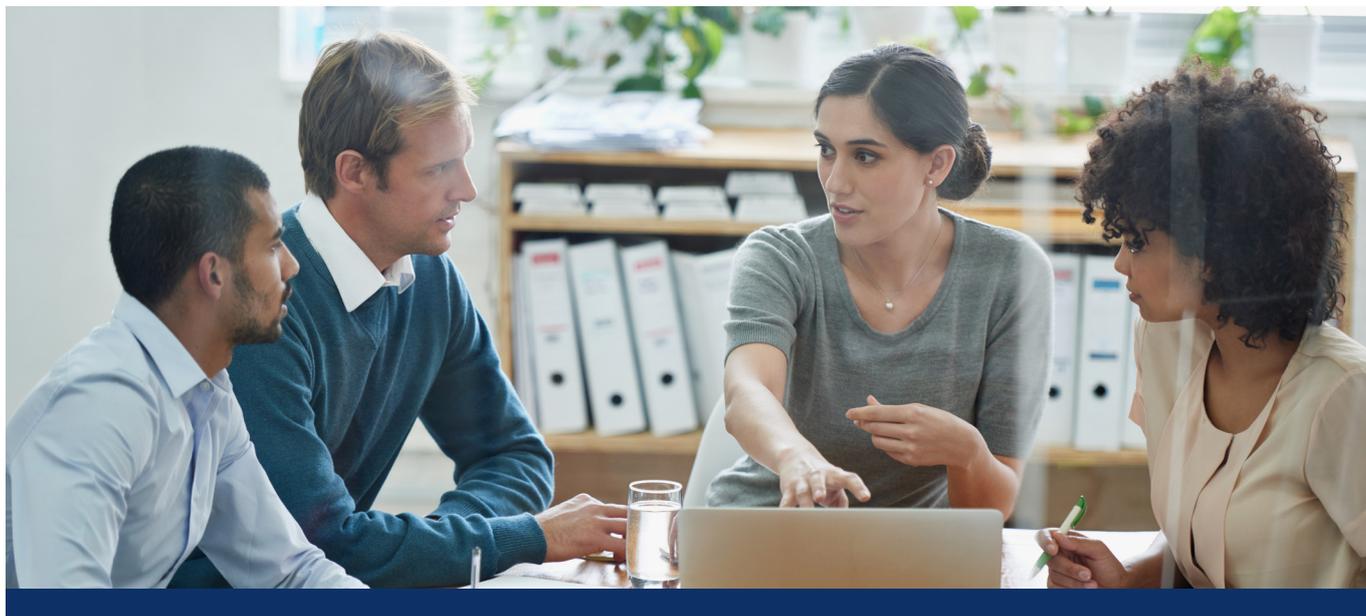
- Study progress reports
- Data collection reports
- Monitoring reports
- Over-read reports



Project Management

Offering a professional and structured approach to the planning, implementation, and completion of studies.

Vitalograph assigns a Project Manager as the primary contact for study sponsors. The PM will take ownership of all Vitalograph deliverables and liaise across Vitalograph functions to coordinate agreed outputs. Project Managers are supported by Senior Project and Program Managers to ensure studies run efficiently, with risks monitored, and customer needs reflected at all times.





Expert Clinical Advice

People you can trust.

You will have access to our in house clinical experts and Respiratory Physiologists as well as a network of key opinion leader associates to support with planning, specification and protocol design. If required, your Key Account Executive will link you to the right expertise for your study to offer advice on a range of issues e.g. endpoints, safety, compliance, monitoring, interpretation of data or recruitment.



Clinical Over-Read

Clinical experience for quality assured data.

Vitalograph provides over-reading (data QA) services for all key endpoint data collected by our systems including Spirometry, DLco, Respiratory Muscle Strength Assessment, Lung Volumes and ECG.

Centralised data is reviewed by a team of experts trained in the protocol, test type and experienced in the therapeutic area.

Study data is monitored for its quality and validity in accordance with the latest guidelines. Quality metrics are provided via a feedback loop to support sites in improving and producing quality data and the rapid turn-around of reviews can support screening decisions. This ensures that endpoints are acceptable against guidelines for a high quality dataset.

Over-Read 360

Our specialist Over-Read 360[®] utility in Spirotrac allows pulmonary function test data to be reconciled to check that site best test parameter and over-read data agree. Over-Read 360 provides quality assurance of data for endpoint analysis against recognised guidelines. Over-Read 360 automatically consolidates over-read responses so that site data always reflects the correct results. Data variability and reconciliation efforts are reduced by ensuring that site staff receive the best quality data and feedback in a timely manner. Our over-readers proactively assess any need for additional coaching of sites or site staff to keep studies on track.





Training

Quality training, assured endpoints.

Vitalograph considers site training a priority to reduce variability and promote a uniform approach to the study. Good training is key to assuring quality data. Training is offered before and during studies through a range of flexible media to meet your study needs.

Working together with the Vitalograph Clinical and Project leads, our experienced Training Manager makes recommendations for training based on study design, protocol, and site experience. Training results are monitored and feedback provided on metrics such as completion, performance, and trends.

Ongoing Training Support

We offer refresher training for long-term studies and repeat training to allow for site and staff turnover as well as booster training where specific need is identified. We also offer respiratory awareness training for individuals in sponsor teams who wish to learn more before they initiate a study or contract with Vitalograph.



Site Support

Rapid responses to safeguard workflows

Our in-house site support team are the first contact for site staff and CRAs, taking ownership of issues to ease site burden and enable sites to get the best quality data. The site support team have an intimate understanding of study devices, many of which are designed and manufactured by Vitalograph meaning our technicians are able to resolve most issues on the first call.

Site support technicians are trained on the system specifics of each trial so that they can answer questions and offer advice or action to resolve requests for assistance. The team monitors trends to identify risks and works proactively with sites to safeguard workflows.



Centralized Study Solutions



Vitalograph Web Portal

Secure study management hub and technology platform for study delivery, collection and analysis of data.

The Vitalograph Web Portal sits at the heart of Vitalograph's clinical trials solutions.

Empowering Sites. Study delivery is optimised through Vitalograph Web Portal's study specific, user friendly workflows which guide sites through subject and device management activities. eLearning options throughout the study support continuous improvement for optimal data quality and automated alerts assist sites with subject monitoring.

Empowering Sponsors. Results from multiple endpoints may be viewed and monitored by the Sponsor in real-time as data is received into Vitalograph servers. This allows rapid and informed decision making as the study progresses.

Complex made easy.

Streamlining delivery of even the most complex study, the innovative Vitalograph Web Portal is used across Vitalograph's centralized studies, facilitating over-reading and expediting data reconciliation. Each study utilizes a Web Portal instance tailored specifically to meet its protocol requirements.



Reducing time and cost. Study activities are managed centrally and actions relating to the study are automatically recorded. Endpoint data may be viewed securely and contemporaneously to allow timely decision making as your study progresses.

Improving quality. Accurate and complete record keeping enables monitoring of performance of sites and study status. A feedback loop and high quality eLearning options ensure continuous improvement through the study.

The Vitalograph Web Portal provides a secure, study specific facility through which study management activities take place including:

- eLearning
- Localized training materials
- Electronic data reconciliation
- Over-reading and consolidation of results
- Data analysis
- Alerts directly to sites including for remote and home monitoring endpoints
- Study specific reports
- Training completion and recording
- End to end encrypted communications over HTTPS
- 21 CFR 11 Compliant with full audit trail features and electronic signatures
- Supports role-based user access levels
- Clinical data stored on Vitalograph secure servers with multiple secure backup options
- The Vitalograph Web Portal is compliant with or follows all applicable privacy laws and best practice

Clinic Solutions

Clinic Solutions

Centralized endpoints for a more complete data set

With 41+ million operational hours at clinical trials sites, the COMPACT™ Medical Workstation is the proven solution for clinic-based studies. It ensures a cost-effective solution by acting as a hub to centralize subject management, integrating data from Vitalograph and 3rd party devices to provide a complete centralized repository for clinical data based on study requirements.

- Supplied as a system with other devices
- Bluetooth and USB connectivity



The COMPACT is a validated medical device, featuring a user-friendly interface and integral spirometer. It runs Vitalograph Spirotrac® software, which is adapted to meet specific protocol requirements. Spirotrac software supports automated quality and repeatability feedback based on ATS/ERS guidelines, and streamlines protocol-driven workflows. Data is saved to the device and once transmitted, viewable via the Vitalograph Web Portal.

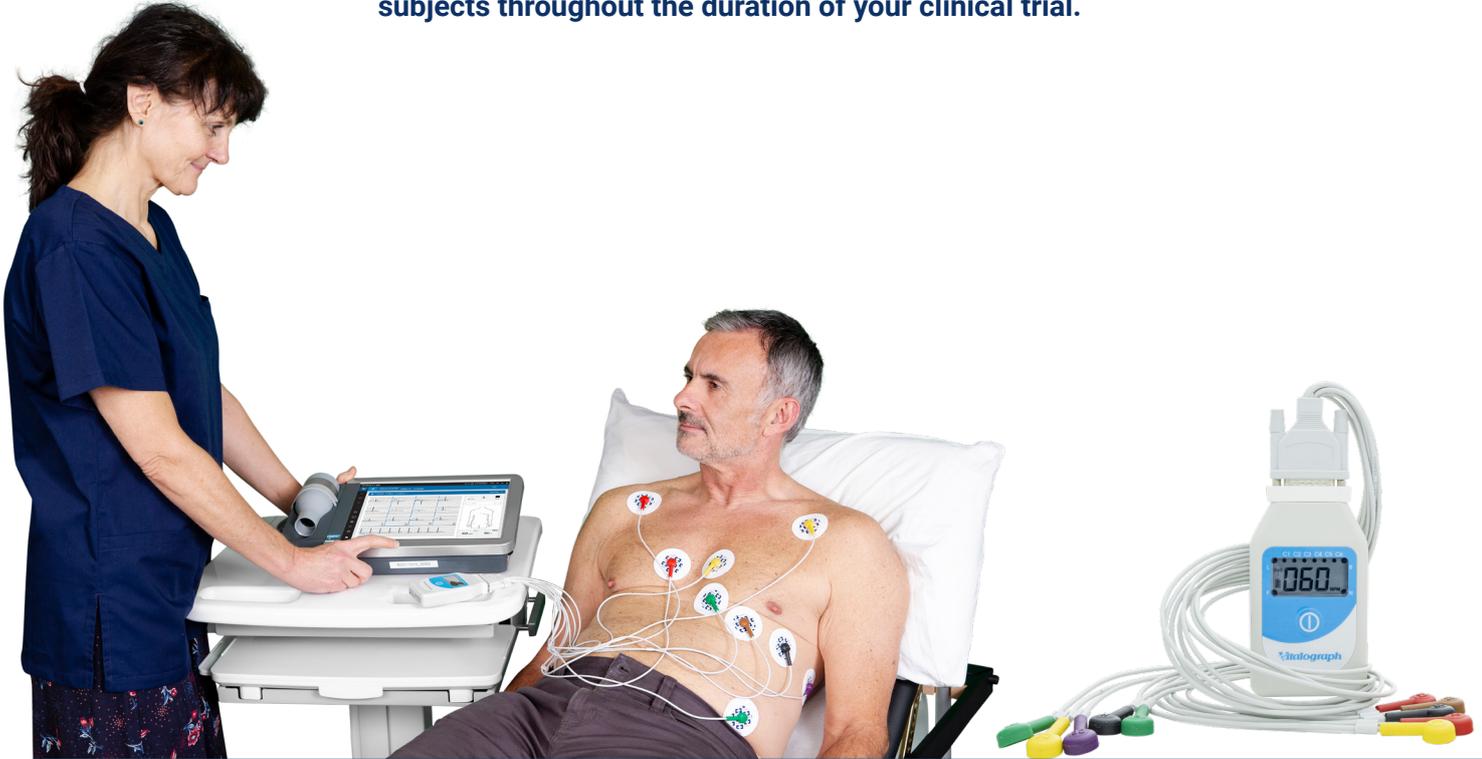
- High-resolution touch screen
- Centralized subject and endpoint management
- Secure, encrypted data transmission direct to Vitalograph data servers via WiFi or wired connection
- Over-Read 360 provides expert analyst review and reconciled feedback for better quality data
- Software adapted to the needs of each study
- Spirotrac meets latest ATS/ERS PFT guidelines
- One device can host multiple protocols
- Automated software updates
- CE Marked and FDA cleared
- Automatically calculates predicted values and % predicted/LLN

Endpoint options include:

- Questionnaires, ePRO & eCOA
- ECG
- DLco
- FeNO
- 6 minute walk test
- Spirometry (FEV1, FVC, FEV/FVC, Flow parameters, % Predicted, LLN)
- Lung Volumes (TLC, FRC, VC)
- Respiratory Muscle Strength (including MIP/MEP, SNIP, PCF, IFR)
- SPO₂
- Blood Glucose
- Blood Pressure

Cardiac Safety

Expert cardiac analysis and a choice of ECG devices are available to ensure accurate endpoint data such as QT/QTc, as well as provide timely interpretations and alerts to support safety monitoring of subjects throughout the duration of your clinical trial.



Inhaler Training

Assess inhaler technique and train subjects in MDI or DPI inhaler use to help ensure effective drug delivery

The Aerosol Inhalation Monitor (AIM™) is recommended to complement clinical trials where other Vitalograph devices are used to capture in-clinic or at-home respiratory endpoints.



It is especially useful to mitigate reduced therapeutic efficacy due to poor inhaler technique.

The AIM indicates firing/activation, inhalation flow rate and breath hold which are critical to ensure drug is not wasted and subjects get the best from the prescribed dose. The device is easy-to-use and is an excellent tool to help ensure that subjects leave the clinic knowing how to effectively self-administer inhaled therapies.



Cough Monitoring Solutions

Cough Monitoring Solutions

Validated system for objective measurement of cough



Cough Monitoring



Vitalograph
Web Portal



Cough Analysis

The VitaloJAK® Cough Monitor provides the only fully validated system for objective measurement of cough. The ambulatory VitaloJAK device can be worn at home and allows the subject to continue normal daily activity during assessment. Cough recordings of up to 24 hours undergo centralized, semi-automated analysis to provide efficient and rapid quantified data. The device is CE marked and FDA cleared.

Data generated by the system is proven to have median sensitivity >99% and excellent integrity. VitaloJAK's patented chest sensor overcomes cough suppression and mask muffling for reliable, highly accurate cough counts. The system has been used for research since 2005 and in phase 2 and 3 studies globally since 2014.

Using analysis software and processes developed in partnership with internationally renowned cough researchers working at Manchester University NHS Foundation Trust, the VitaloJAK system comprises 3 distinct components, all essential to ensure high quality data:

- VitaloJAK high fidelity cough monitoring device and test kits
- Vitalograph Web Portal to collect, manage analysis and report cough data
- Cough Analysis including event markers for awake and sleep periods



Remote Monitoring Solutions

Mobile Clinic Endpoints

Enabling centralized endpoint collection away from the clinic

Vitalograph's suite of connected mobile medical devices send encrypted data to the Vitalograph Web Portal meaning that clinic endpoints are centralized from wherever they are collected. These solutions are particularly well suited to studies using mobile research nursing teams or off-site clinics.

Endpoints available for remote clinic monitoring include:

- Spirometry
- ECG
- eCOA
- Sponsor questionnaires
- Pulse Oximetry
- Blood Pressure
- Blood Glucose

Home Monitoring Endpoints

Intuitive devices for monitoring endpoints at home

The ability to monitor subjects at home is now more important than ever. Home monitoring can help ensure the progress of a study where clinic visits are restricted. Moreover it can provide a richer and more complete understanding of subjects' conditions and responses through higher frequency of data collection than is possible through clinic visits alone.

Vitalograph offer a range of easy-to-use remote monitoring devices suitable for home use specialising in respiratory endpoints including:

- ePRO
- Sponsor questionnaires
- Respiratory endpoints e.g. PEF, FEV1, FVC
- Cough
- Remote coaching options



In2itive e-Diary

Next generation eCOA platform with integrated respiratory assessment

The In2itive™ e-Diary is a robust handheld medical device with a high resolution touchscreen for gathering eCOA data. Using Vitalograph's proven Fleisch Pneumotachograph flowhead, the In2itive e-Diary provides accurate measurement of respiratory endpoints in clinic or home settings.

Fully integrated wireless communications allow automatic secure transmission of data to the study web portal. Uploaded data is available for instant review of site and subject performance. The In2itive e-Diary is a fully validated class II (USA) and IIa (EU) medical device meeting or exceeding all technical requirements for cyber-security and data protection.

- Large, responsive touchscreen
- Fleisch pneumotachograph flowhead for respiratory endpoints e.g. FEV1 and PEF
- Customizable alerts, reminders, and workflows to fit study protocols
- Date/time stamps on all data and results
- Cellular/Mobile option transmits results direct to Vitalograph web portal
- Automatic secure end-to-end encrypted data transmission
- Live spirometry quality feedback
- Subject management via web portal or Spirotrac software
- Integrated animated training module
- Password protected
- CE marked and FDA cleared



The device can host ePRO, eCOA or sponsor questionnaire using text, VAS, images, tick box, radio buttons, etc. Pre integrated & validated ePROs:

Respiratory - asthma

- ACQ
- AQLQ(S)12+
- AQ20
- ACT

Respiratory - COPD

- AQ20
- EXACT
- EXACT E-RS
- CAT

Health status

- EQ5D-3L
- EQ5D-5L

60 years of experience in respiratory diagnostic innovation enables us to offer novel solutions to meet evolving study needs. We listen to what you value, then configure, customize and create solutions designed specifically for the needs of your protocol, investigators and patients.

Speak with our business development team to discuss your study requirements.

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