Innovative modularity and networking for truly customised Pulmonary Function Testing solutions

“Respiratory care, when breath does matter”
Quark PFT is a modular and compact Pulmonary Function Testing system that allows accurate, repeatable, low cost tests over time. It has been designed to meet any physician's configuration requirement, whether a full-featured PFT system or a basic configuration to start a private practice is needed.

Quark PFT is powered by OMNIA, the new software platform, entirely designed and developed by COSMED. OMNIA provides an innovative and user-friendly interface (touch-screen ready) that allows operators to navigate and access features and testing with a minimal amount of training. OMNIA is available in a multi-language environment either as a stand-alone or as a client in a small or large network environment.

All Quark PFT modules comply with the latest published ATS/ERS statements.

**Flowmeters available with Quark PFT and their main features**

<table>
<thead>
<tr>
<th>Flowmeter</th>
<th>X9</th>
<th>Turbine 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
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<td>User Linearization</td>
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<td>Environmental sensitivity</td>
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<td>Ideal for</td>
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<tr>
<td>Independent validation</td>
<td>X9</td>
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</table>

Design

- True modular design architecture. It allows to configure Quark PFT according to any kind of requirement. This cost-effective solution gives the opportunity to scale at any time to a more complex configuration.

- Low running costs. The design architecture has been made to eliminate the procedure of ordinary maintenance and to easily and rapidly solve any technical problem by replacing a board.

- Powered by OMNIA. A contemporary, simple and ergonomic software interface with intuitive workflow and hierarchy, OMNIA is based on standard SQL database to store unlimited data securely and guaranteeing lifetime data ownership.

- Simplified workflow. OMNIA user interface and its workflow management have been designed to simplify procedures and to reduce testing time.

- Quick and easy calibration procedures. Quark PFT includes both standard calibration procedures (ie flowmeter and gas sensors) and advanced calibration procedures to verify accuracy, including Pneumotach linearization and verification of all flowmeters (turbine, PNT).

- Automatic interpretation of tests. Based on latest scientific guidelines supported by a powerful algorithm that automatically process results and provides interpretation text strings, including numerical results and graphical data presentation (pictograms).

- Network ready. OMNIA is available both as a single stand-alone workstation or in a client/server configuration for small or very large network environments.

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"ERS 2004: Lung function testing equipment: a manufacturer’s unbiased viewpoint” K. Hogben, 2004 ERS Buyers’ Guide to Respiratory Care Products p. 42-64
Spirometry

Quark PFT in its basic configuration includes all features and hardware for spirometry testing (FVC, SVC, MMV and Pre/Post Bronchial Provocation).

- Choice of different flowmeter configurations (pneumotach or turbine).
- New Trial Selection and Quality Control functions (in compliance with ERS/ATS guidelines).
- Innovative pediatric incentivation with user defined effort grade on both volume and flow.
- Full compliance with “2005 ATS/ERS consensus” (Interpretation, QC, etc.).
- GOLD COPD Interpretation on FVC PostBD.
- Automatic control of the Broncho-Challenge protocols with an integrated dosimeter (option).
- Latest Global Lung Initiative (GLI) predicteds (including Z-score).
- Possibility to download Six Minute Walk Test data from any Spiropalm 6MWT.

Body Plethysmography (TGV/RAW)

“Gold Standard” lung volume measurement can be performed with the addition of a variable-pressure plethysmographic body box module. The large cabin provides comfort and ease-to-access both for adults and special populations.

- Large constant-volume cabin (873 liters).
- Quick calibration and fast stabilization times.
- Ultimate pressure sensor transducers ensure maximum sensitivity with severe patient’s response (range ±1 cm H₂O).
- User-defined testing sequence (TGV, sRAW, SVC, IC).
- Real time review on all performed TGV and RAW captures.
- Calibration procedures include body box leakage check and polytropic factor.
- Advanced Edit function for tests/trials/captures.
- Automatic interpretation statements according to measured TLC (restriction confirmed).
- Possibility to capture multiple RAWs with one single click (up to 7).
- TLC can be calculated with an Inspiratory Capacity (IC) manoeuvre other than a complete SVC manoeuvre (TLC=TGV+IC).
- Different RAW algorithms available (sRawTOT, sRawins, sRawexp, sRawIC, sRawR tot, sRawRins).

Spirometry (FVC) review results

Innovative pediatric incentivation with selectable effort grade for both FVC and PEF parameters

Body Plethysmography (TGV/RAW) real-time
Lung Diffusing Capacity (DLCO)
The DLCO module allows the diffusing capacity of Carbon Monoxide (CO) in the lungs with different test options: single-breath, intrabreath and membrane diffusion. The measurement is made possible through the continuous analysis of CO and CH$_4$ (tracer) fractions with the fastest-in-the-market NDIR analyzer.

- CO analyzer designed specifically for DLCO and thus independent from exhaled CO$_2$.
- “0 wet” correction to compensate CO backpressure and humidity interference.
- DLCO advanced edit feature (automatic and custom selection of washout and alveolar gas volume).
- Mouth pressure signal during DLCO (Single breath only).
- Software shows clinically relevant parameters (DLCO_corr, DLCO/VA) as pictograms.
- Estimated TLC during DLCO corrected for obstructive patients.
- Membrane Diffusion automatically enabled whenever multiple DLCO$_{sb}$ or DLCO$_{ib}$ manoeuvres are performed.
- Test simulation (without using gas mixture) to coach subjects before testing.
- Both automatic system and user defined DLCO quality control grading
- Breath hold time settings according to various standards (Jones, Ogilvie, ESP).

Lung Volumes (FRC - Nitrogen Washout)
The lung volumes module adds the possibility to test Functional Residual Capacity (FRC) via single or multi-breath Nitrogen Wash-out.

- Use of fast and accurate O$_2$ and CO$_2$ analyzers (no conventional N$_2$ analyzer required) simplifies ordinary maintenance and calibration procedures.
- Possibility to detect automatically or manually the 4 phases composing the wash-out curve, including the slope of the alveolar plateau.
- Real time N$_2$ Wash-Out plot together with several indicators for the control of the respiratory pattern.
- Quality control messages during test maneuver (wash-out pattern).
- Automatic detection of washout curve phases (N$_2$WO Single Breath).
- Lung Clearance Index (LCI)
- Adjust the end of the test criteria (entire manoeuvre vs. user selection) in case of leaks occurred during testing (N$_2$WO Multi-Breath).
- Visual leak detection by real-time FetN$_2$ plot.
- Possibility to perform SVC separately.
- Latest Predicteds: ERS 93, Chhabra India, Gutierrez (Canada), Mary IP (Hong Kong).

Respiratory Mechanics
Available as standard testing feature together with the Q-Box standalone body plethysmography (or the Q-Box module) or as an optional module to the Quark PFT. The respiratory mechanics module includes:

- Maximal Inspiratory Pressure (MIP) and Maximal Expiratory Pressure (MEP).
- Respiratory Drive assessment (P0.1)
- Intuitive display of all accepted maneuvers with an histogram chart (different color for Expiratory and Inspiratory maneuvers).
- Compliance with 2001 ATS/ERS guidelines (one second average around peak value).
- Available Predicteds: Black Hyatt, Evans, Neder.
Airway Resistance (Rocc)

The Occlusion Technique (Rocc) is fast and reliable, more suitable for airway resistance measurement in patients unable to perform body plethysmography (critically ill, children). The patient will be asked to breathe spontaneously through a mouthpiece while an occlusion valve interrupts the airflow for 100 msec.

- Hardware consists of a special handle incorporating a dedicated low flow PNT and an occlusion valve.
- Possibility to measure Occlusion Resistance pre and post BD (after bronchodilator administration).

Integrated Dosimeter

The optional dosimeter module includes all hardware and software components to run a broncho challenge test by means of an integrated dosimeter. Main features include:

- Automatic control of bronchial challenge tests through a dosimeter.
- DeVilbiss 646 Nebulizer, powered by dry compressed air.
- Automatic measurement of the actuation time of the dosimeter valve with a resolution of 10 ms.
- Provided with a database of standard (ATS “Five breaths” and Lofarma) and user defined protocols.
- Multi-step protocol with a single drug concentration.
- Easy to clean and disinfect.
Metabolic (CPET/REE)
Quark PFT can be easily transformed in a compact metabolic cart for the assessment of pulmonary gas exchange and ventilatory responses during clinical exercise test. High quality components and super-fast analyzers ensure unsurpassed accuracy, reliability and real breath-by-breath analysis.

- Breath by Breath (BxB) metabolic module for both Cardio Pulmonary Exercise Test (CPET) and Resting Energy Expenditure (REE) assessment.
- Latest gas analyzers technology: para-magnetic, stable and durable for the $\mathrm{O}_2$, rapid infrared for the $\mathrm{CO}_2$.
- Ergonomic multi-use silicone Face Masks (available in 5 sizes: 3 adult, 2 pediatric) for comfortable testing in any conditions.
- Independently validated on a wide range of test modes (for both exercise and resting applications) and exercise intensities.

OMNIA Metabolic Software
- Easy data and graphs display through either pre-defined Dashboards (9 panel plot, etc.) or user defined templates.
- Comprehensive interpretation tool with a powerful algorithm automatically elaborating results and providing interpretation text strings including numerical results.
- Real time acquisition and capture of Exercise Flow-Volume loops (EFVL) for the evaluation of ventilatory limitation.
- Multi-layers environment allows multiple views easy to access either by a click of the mouse or simply sliding the finger on a touch-screen device.
- Built-in Protocol editor (graphical) to design any type of exercise protocol (for both bikes and treadmills).

Access data in spreadsheet format for advanced data elaboration (filtering, smoothing, etc.).
- Ergometer Control, via RS-232 interface, allows user easy protocol setup and dynamic changes.

Accessories and Options
- Integrated diagnostic quality 12lead Stress ECG, either in wireless or patient cable configurations.
- 7L Mixing Chamber for gas exchange analysis of low and high ventilation ranges.
- Integrated Pulse Oximeter monitors (Nonin® technology) with a broad range of sensors (finger, earlobe or forehead/reflectance).
- Canopy Hood for Gold Standard Resting Energy Expenditure (REE) measurements on spontaneously breathing subjects by means of a ventilated canopy hood.
- Integration with Blood Pressure (Tango) and Cardiac Output (Physioflow) monitors
- High FiO2 kit for gas exchange measurements using hypoxic and hyperoxic gas mixtures.
- Wide selection of ergometers, available from COSMED, including treadmills, cycle-ergometers, arm-ergometers and recumbent bikes, suitable for any clinical and research application.
Networking

OMNIA Network allows to share a single database in either a small network (LAN) or a large network (WAN) environment.

OMNIA Network is based on a Client/Server architecture and allows to run different COSMED devices through simultaneous access of data and run tests via a virtually unlimited number of COSMED products.

- The network license includes five clients (simultaneous access) and can be extended with the purchase of additional single licenses.
- A user management system allows to define users (Physician, Technician, Administrator, etc.) and roles (which specific feature can a user access).
- OMNIA can exchange data with Hospital Information Systems (HIS) via HL7, GDT and with a proprietary Protocol (OCP).
- With the optional HL7 module (either standalone or network) OMNIA allows to get data from an HL7 worklist and send results back to Electronic Medical Records (EMR) and Hospital Information Systems (HIS).
- OMNIA Network runs on Windows Server 2008 (SP2, R2 SP1) and 2012.
- Based on standard SQL database (Express or Standard) to store data securely.

*9 Panel Plot" CPET printout results
Technical Specifications

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>REF</th>
</tr>
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<tbody>
<tr>
<td>Quark PFT</td>
<td>Pulmonary Function Testing Laboratory</td>
<td>C09072-02-99</td>
</tr>
<tr>
<td>Standard packaging</td>
<td>Unit, Smart Valve, Calibration Syringe (3 liters), Nose clips (2 pcs), OMNIA PC software, adapters, cables, probes and user manual</td>
<td></td>
</tr>
</tbody>
</table>

Standard Tests

| Spirometry            | Forced Vital Capacity (FVC) Pre/Post, Slow Vital Capacity (SVC) Pre/Post, Maximum Voluntary Ventilation (MVV), Bronchochallenge - Bronchial Dilator/Constrictor test |         |

Flowmeter

| X9 PNT                | Turbine 2000 (optional) |

| Type                  | Lilly multisection plethysmograph, Bidirectional Digital Turbine ID28 |
| Flow Range            | ±0.8-20 l/s |
| Accuracy              | ±2% or 20 ml/s (flow) ±2% or 200 ml/min (ventil.) |
| Resistance            | <1 cm H₂O/0.1 l/s @ 14 l/s |
| Volume range          | 0.08-300 l/min |

Gas Analyzers

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<th>CO₂</th>
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<td>Module</td>
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<td>Metabolic, N WO</td>
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<td>Type</td>
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<td>NDIR</td>
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<tr>
<td>Range</td>
<td>0-100 %</td>
<td>0-10 %</td>
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<tr>
<td>Accuracy</td>
<td>±0.1 %</td>
<td>±0.02 %</td>
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<tr>
<td>Response time</td>
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<td>100 ms</td>
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</table>

Hardware

| Dimensions & Weight   | 33 x 41 x 16 cm / 11 Kg |
| Interface ports       | USB A-B, RS-232, HR-11, SpO₂ |
| Electrical requirements | 100-240 V ±10 %, 50/60 Hz |
| Environmental conditions | Temperature 10-40°C, Barometer 400-800 mmHg, Humidity 30-90% |

Software

| OMNIA                 |         |

| Available languages   | Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese (Traditional & Simplified), Korean, Romanian, Polish, Czech, Norwegian, Hebrew |

Optional HW Modules

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<thead>
<tr>
<th>Module</th>
<th>Description</th>
<th>REF</th>
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<tr>
<td>Body Plethysmography</td>
<td>Lung Volumes (TGv, TLC, FRC), Airway Resistance (RAW, sRAW, GAW, sGAW), Respiratory Mechanics (MIP/MEP, P0.1)</td>
<td>C03251-01-11</td>
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<tr>
<td>Lung Diffusing Capacity</td>
<td>Lung diffusing capacity (DLCO single-breath, DLCO intrabreath and DLCO membrane diffusion)</td>
<td>C03240-01-11</td>
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<tr>
<td>Lung Volumes N WO</td>
<td>FRC by Multi-Breath Nitrogen Wash-out, Closing Volume by Single-Breath 100% O₂</td>
<td>C03255-01-11</td>
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<tr>
<td>Respiratory Mechanics</td>
<td>Maximum Inspiratory/Expiratory Pressure (MIP/MEP), P0.1</td>
<td>C03257-01-11</td>
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<tr>
<td>Airway resistance</td>
<td>Occlusion Resistance measurement (Pre and Post Bronchodilatation)</td>
<td>C02700-01-11</td>
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<td>Forced Oscillation</td>
<td>Whole lung respiratory resistance by FOT (Total Respiratory System Impedance Zrs, Resistance R &amp; Reactance X)</td>
<td>C09010-01-99</td>
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<td>Integrated Dosimeter</td>
<td>Mannitol, metacholine bronchochallenge with integrated DeVilbiss 664 Nebulizer</td>
<td>C03250-01-11</td>
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<td>Metabolic (CPET/RE)</td>
<td>Cardio Pulmonary Exercise Test (VO₂ max, Anaerobic Threshold), Indirect Cardiac Output (Wassermann), Indirect Calorimetry (REE/RMR, RQ, Energy substrate utilization)</td>
<td>C03254-02-11</td>
</tr>
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</table>

Safety & Quality Standards

| MDD (93/42 EEC), FDA 510(k), EN 66001-1 (safety) / EN 66001-1-2 (EMC) | Complies with ATS/ERS 2005 guidelines |

Bibliography

- Spirometry

- Bronchochallenge

- Body Plethysmography

- Lung Diffusing Capacity
  - "2017 ERS/ATS standards for single-breath carbon monoxide uptake in the lung." BL Graham et al - Eur Respir J. 2017 Jan 3;49(1)

- Nitrogen Washout (FRC)
  - ATS/ERS Consensus statement for inert gas washout measurement using multiple and single breath tests. Eur Respir J 2013; 41: S07-S22

- Forced Oscillations Technique (FOT)

- Respiratory Mechanics

- Metabolic


  - ATS/ERS Consensus statement for inert gas washout measurement using multiple and single breath tests. Eur Respir J 2013; 41: S07-S22


