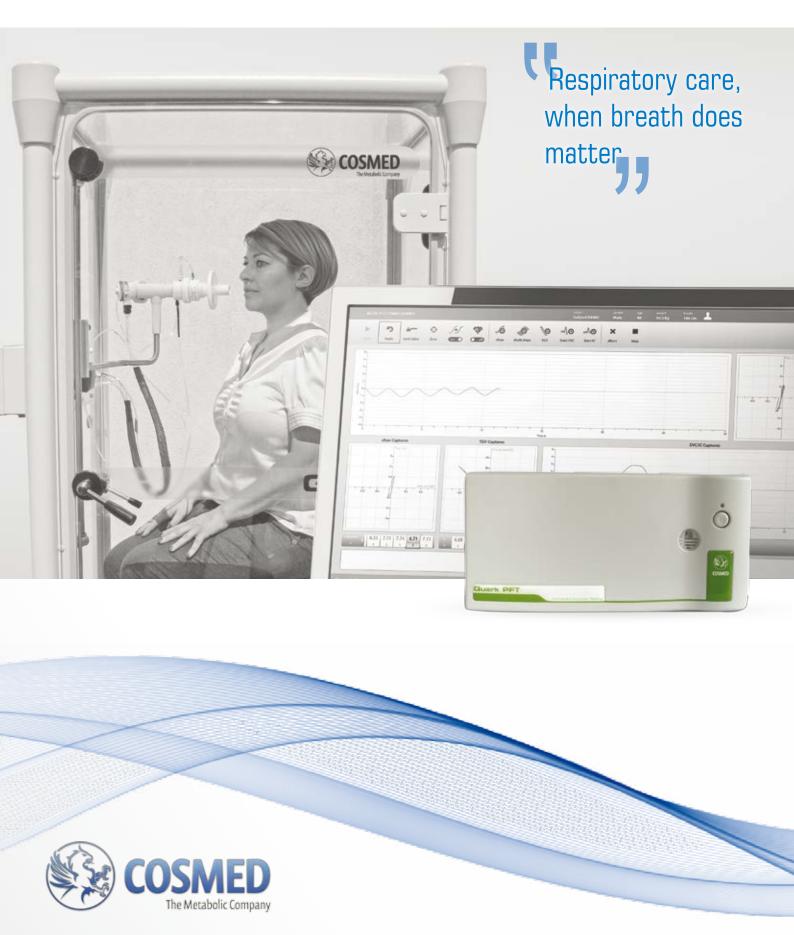


Pulmonary Function Testing

Innovative modularity and networking for truly customised Pulmonary Function Testing solutions



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Full laboratory system that maximise the technology and testing abilities to give all-round performance, high-quality measurements and excellent repeatability⁽¹⁾

- Spirometry
- Body Plethysmography
- Lung Diffusing Capacity
- Nitrogen Washout & Closing Volume
- Forced Oscillations Technique
- Respiratory Mechanics
- Airway Resistance (Rocc)
- Integrated Dosimeter
- Metabolic testing (CPET/REE)



Quark PFT is the modular Pulmonary Function Testing laboratory from COSMED, designed to meet the needs of the modern physicians who invests before spending. Whether you need a complete PFT system or a basic configuration to start your own practice, Quark PFT can be tailored to any requirement and application. Instantly upgrade your Quark PFT without having to send it to the manufacturer, thanks to an innovative "plug and play" design. Low maintenance costs, no need for technical expertise and user-friendly software, make Quark PFT the perfect tool for accurate and reliable data in any hospital department or physician's office.

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

Design

- True modular design architecture allows to configure Quark PFT selecting only the required test features. This cost-effective solution gives the opportunity to scale at any time to a more complex configuration. "Plug and play" circuitry allows instant upgrades without the need of technical support.
- 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.
- Latest technology in flowmeters, gas analysers and other hardware components (ie COSMED patented smart shutter valve), allows accurate measurements and fast test procedures.
- Simplified workflow for improved pulmonary function tests workaround. Quark PFT with the new OMNIA software is an easy and straightforward solution for save and efficient transmission, interpretation and billing of tests performed inside an organisation, contributing to improved efficiency and reduction of errors.

Quick and advanced calibration procedures for high accuracy measurements either for flowmeters (calibration and linearity check), gas sensors (zero, gain and delay) and body box (box leakage and the polytrophic factor).

X9 PNT	Digital Turbine
Lilly type pneumotach	Bi-directional turbine
Accurate through a wide ventilation range	Good linearity at any ventilatory range
Easily maintainable and reliable through many tests	Durable, virtually maintenance-free
3 litres syringe calibration (required every day)	3 litres syringe calibration (required once a week)
Linearize the flowmeter at any time with OMNIA software	No need for linearization
Extremely low thermal capacity (no condensation during expiration)	Measurement insensitive to humidity and gas composition
Only option for body plethysmography. Best solution for spirometry	Best solution for exercise testing
Independently validated for spirometry and DLCO (Hans Rudolph Inc., 2012)	Independently validated for spirometry (LDS Hospital, 2004)

Flowmeters available with Quark PFT and their main features

- Powered by OMNIA software with innovative user interface, touch screen, easy-to-use and self-explanatory. Compatible with Win 8 PRO (32/64), Win 7 (32/64), Win Vista (32/64).
- Comprehensive interpretation tool with a powerful algorithm automatically elaborating results and providing interpretation text strings including numerical results. Graphical data presentation both at screen and on printouts with gauges (pictograms).

Spirometry

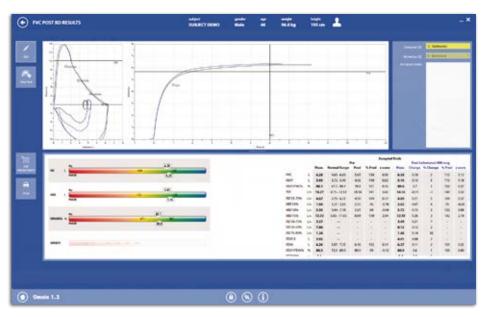
The basic configuration of Quark PFT includes all features and hardware for spirometry testing (FVC, SVC, MMV and Pre/Post Bronchial Provocation).

- Choice of different flowmeter configurations (PNT or turbine)
- New Trial Selection and Quality Control functions (in compliance with ERS/ATS guidelines)
- Innovative pediatric incentivation with selectable effort grade
- Full compliance with "2005 ATS/ERS consensus" (Interpretation, QC, etc.)
- GOLD COPD Interpretation on FVC PostBD
- Latest Global Lung Initiative (GLI) predicteds (including Z-score)
- Possibility to download Six Minute Walk Test data from any Spiropalm 6MWT

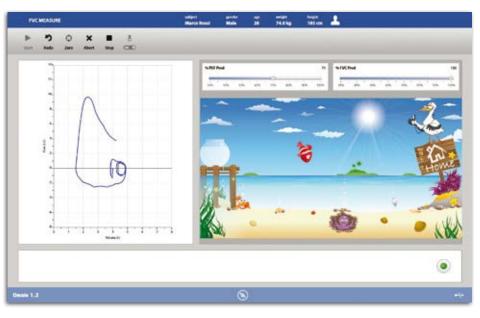
Body Plethysmography (TGV/RAW)

"Gold Standard" lung volume measurement can be performed as a Quark PFT module with the addition of a variable-pressure plethysmographic body-box with extremely fast times of stabilisation and calibration. The large cabin provides comfort and ease-to-access both for adults and special populations.

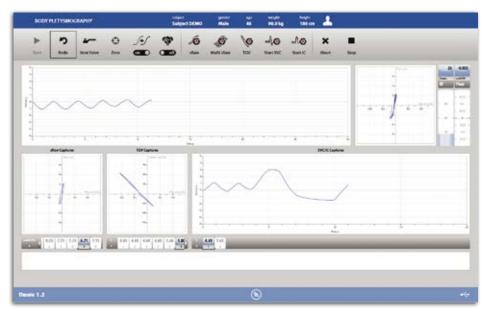
- Large constant-volume cabin (873 litres)
- Ultimate pressure sensor transducers ensure maximum sensitivity with severe patient's response
- User-defined testing sequence (TGV, sRAW, SVC, IC)
- Real time review of all previously performed captures
- Advanced Edit function for tests/trials/ captures
- Automatic interpretation statements according to measured TLC (restriction confirmed)
- Possibility to capture multiple RAWs with one single click (up to 7)



Spirometry (FVC) review results



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



Body Plethysmography (TGV/RAW) real-time dashboard

- TLC can now be calculated with an Inspiratory Capacity (IC) manoeuvre other than a complete SVC manoeuvre (TLC=TGV+IC)
- Different RAW algorithms available (sRawTOT, sRawins, sRawexp, sRaw0,5, sRaw0,2, sRawFmax)
- Latest Predicteds: ERS93/ECCS, Roca/ ECCS, Koch 2012, Garcia-Rio
- Simulated test with optional Erlenmeyer Flask

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 fractions and methane (CH4 the tracer) with two extremely fast infrared analyzers.

- CO analyzer independent from CO₂ presence in gas sample (therefore additional CO₂ analyzer not required)
- "0 wet" correction to compensate CO back pressure 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)
- Clinically relevant parameters (DLCO_ corr, DLCO/VA) reported 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
- DLCO Quality Control grading
- Specific X9 linearization table for improving accuracy of inspiratory volume during DLCO
- Breath hold time settings according to different standards (Jones, Ogilvie and ESP)
- Latest Predicteds: ECCS, Crapo and Morris, Paoletti, Roca, Knudson

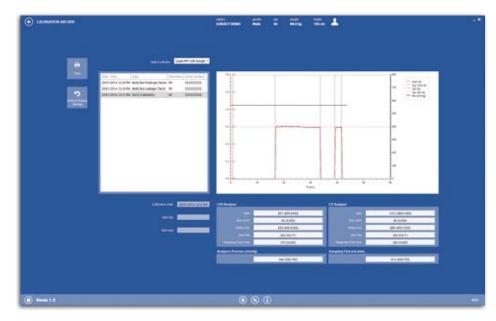
Lung Volumes (FRC - Nitrogen Washout)

The lung volumes module adds the possibility to test Functional Residual Capacity (FRC) via multi-breath Nitrogen Wash-out or singlebreath 100% O_2 techniques. More affordable alternative to body plethysmography for lung volume measurement (ATS/ERS guidelines)

- Use of fast and accurate O₂ and CO₂ analyzers (instead of the conventional N2 analyzer) simplifies significantly 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



Lung Diffusing Capacity (Single breath technique)



DLCO calibration history log

- Real time N2 Wash-Out plot together with several indicators for the control of the respiratory pattern
- Quality control messages during test manoeuver (wash-out pattern)
- User defined Multi axis graphs during and after test execution
- Visual leak detection by real-time FetN₂ plot.
- Possibility to perform SVC separately

Respiratory Mechanics

The respiratory mechanics module enables the execution of tests for the evaluation of respiratory muscles strength and their severity.

- Also included with the Body-Box module
- Minimal Inspiratory Pressure (MIP) and Maximal Expiratory Pressure (MEP)
- Respiratory drive (P0.1) performed either with or without elevated inspiratory CO₂

Forced Oscillation Technique (FOT)

For the assessment of mechanical properties of total respiratory input impedance (Zrs) under tidal breathing conditions

- Great accuracy and reproducibility
- Fast (8 seconds only) and easy
- Ideal for uncooperative subjects or patients unable to perform forced expiratory manoeuvres
- Pseudo random noise signal (frequency range from 4 to 48Hz)
- Adjustable arm for maximum comfort during testing

Interrupter Technique (Rocc/Rint)

Measurement of respiratory resistance through the interrupter technique. Tidal breathing through a mouthpiece while an occlusion valve interrupts the airflow.

- Rocc, RoccEX, RoccIN, Gav, etc.
- Low patient collaboration required (ideal for testing children)
- Limited capital investment (good alternative to body plethysmography)
- Easy to mount and to disinfect

Integrated Dosimeter

Controlled and more accurate management of bronchial challenge tests with an integrated DeVilbiss 646 Nebulizer, powered by dry compressed air.

- ATS ("Five breaths"), Metacholine-dose, Mannitol and user defined Bronchochallenge protocols
- Multi-step protocol with a single drug concentration
- Easy cleaning and disinfecting

Integrated Pulse Oximeter (SpO,)

Digital pulse oximetry capabilities can be easily integrated with Quark PFT system for the measurement of oxygen saturation during rest or during exercise.

- High quality integrated monitors (Nonin© technology)
- Broad range of accurate and dependable sensors (finger, earlobe or forehead/reflectance)
- Low power draw (60 mW) and intelligent pulse-by-pulse filtering



Forced Oscillations Technique (FOT) the best way to lung function assessment in children



Airway resistance by the Interrupter Technique (Rocc/ Rint)



5

Integrated pulse oximetry (SpO₂) for measurements at rest or during exercise.

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 analysers assure unsurpassed accuracy, reliability and real breath-by-breath analysis.

- Latest technology in gas analyzers: paramagnetic, stable and durable for the O₂, rapid infrared for the CO₂. Both analyzers are reliable and do not need maintenance for long periods.
- Breath by Breath (BxB) sampling technique (with Face Mask) either during exercise or at rest
- Ergonomic multi-use silicone Face Masks (available in 5 sizes: 3 adult, 2 pediatric) for comfortable testing in any conditions
- Ergometer Control, via RS-232 interface, allows user easy protocol setup and dynamic changes
- Independently validated technology on a wide range of test modes and exercise intensities

OMNIA Metabolic Software

OMNIA PC software provides a user friendly, fully-customisable interface together with powerful data elaboration

- Automatic and manual detection of anaerobic threshold according to the modified V-Slope method (Wasserman)
- Access data in a spreadsheet format for advanced data elaboration (filtering, smoothing, etc.)
- Standard and custom exercise protocols design



Cardio Pulmonary Exercise Test (CPET) real-time dashboard 9 Panel plot

- O₂ Kinetics feature automatically provides O₂ debt, O₂ deficit and tau values during any constant stage
- Indirect Cardiac Output by "Wassermann Algorithm"

Metabolic Accessories and Options

The system can be implemented with a broad range of options/accessories that allow to configure a fully integrated Cardio Pulmonary Exercise Testing (CPET) system with 12lead stress test PC ECG or to perform Gold Standard indirect calorimetry tests.

- Integrated diagnostic quality 12-lead Stress
 ECG, either in wireless or patient cable configurations
- 7L Mixing Chamber for gas exchange analysis of low and high ventilation ranges

- **Canopy Hood** for Gold Standard Resting Energy Expenditure (REE) measurements on spontaneously breathing subjects by means of a ventilated canopy hood
- High Fi0, kit for gas exchange measurements using hypoxic and hyperoxic gas mixtures.
 - Wide selection of ergometers, available from COSMED, including treadmills, cycleergometers, arm-ergometers and recumbent bikes, suitable for any clinical and research application.



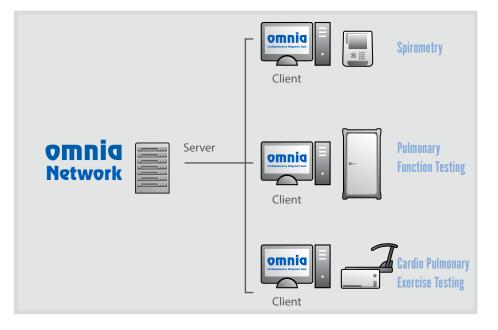
Networking

- Compatible with Windows Server 2008 (SP2, R2 SP1), Server 2012
- Database running on Microsoft SQL database, Express edition for small networks, Enterprise edition for complex hospital networks
- Optional networking module includes 5 clients (with simultaneous access to server). Licenses are not permanently linked to a device. Additional single licenses can be purchased when required.
- Multi-users access rights management (Physician, Technician, Administrator...) with event logging
- GDT data interface included

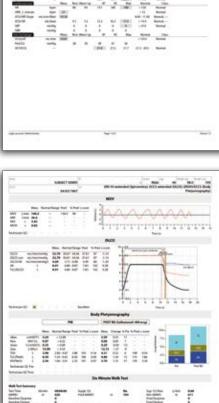
EX; COSMED

 Access and security compliant (according to US HipAA, ISO 27799:2008, EU 95/46/CE and 2002/58/CE)

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- "ERS 2003: The FOT in clinical practice. Methodology, recommendations and future developments", Eur Respir J 2003; 22: 1026–1041

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Technical Specifications

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Product	Description			REF		
Quark PFT	Pulmonary Function Testing Laboratory			C09072-02-99		
Standard packaging	Unit, Smart Valve, Nose clips (2 pcs), USB cable, PC Software (CD-Rom), Calibration Syringe 3L, User Manual					
Standard Tests	indard 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	n (optional)				
Туре	Lilly multiuse pneumotach		Bidirectional Digital Turbine			
Flow Range	0-14 l/s		0-16 l/s			
Accuracy	$\pm 2\%$ or 20 ml/s (flow)		\pm 2% or 20 ml/s (flow) \pm 2% or 200 ml/ min (ventil.)			
Resistance	<1cmH ₂ 0/I/s @ 14 I/s		<0.6 cmH ₂ 0 /l/s @ 14l/s			
Ventilation range	NA		0-300 l/min			
Gas Analyzers		CO ₂	С0	CH4		
Module	Metabolic, LV	Metabolic, LV	DLCO	DLCO		
Туре	Paramagnetic	NDIR	NDIR	NDIR		
Range	0-100%	0-10%	0-0.35%	0-0.35%		
Accuracy	±0.1%	± 0.1 %	± 0.003 %	± 0.003 %		
Response time	120 ms	100 ms	200 ms	200 ms		
Hardware						
Dimensions & Weight	33x41x16 cm / 11 Kg					
Interface ports	USB A-B, RS-232, HR-TTL, SpO,					
Electrical requirements	100-240V ± 10% 50/60 Hz					
Environmental conditions	Temperature 0-50 °C (32 - 122 °F); Barometer 400-800 mmHg; Humidity 0-100%					
Software	OMNIA					
Available languages	Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese, Korean, Romanian, Czech					
PC Configuration	1.4 GHz or faster processor speed. Compatible with Vista (32/64), Windows 7 (32/64), Windows 8 (32/64). RAM 4GB (8GB recommended). 500 MB of free disk space					
Optional Modules	Description			REF		
Body Plethysmography	Lung Volumes (TGV, TLC, FRC), Airway Resistance (RAW,C03251-01-11sRAW, GAW, sGAW), Respiratory Mechanics (MIP/MEP, P0.1)					
Lung Diffusing Capacity	Lung diffusing capacity (DLCO single-breath, DLCO C03240-01-11 intrabreath and DLCO membrane diffusion)					
Lung Volumes	FRC by Multi-Breath Nitrogen Wash-out, Closing Volume byC03255-01-11Single-Breath 100% 022					
Respiratory Mechanics	Maximum Inspiratory/Expiratory Pressure (MIP/MEP), Respiratory Drive (PO.1)			C03257-01-11		
Forced Oscillation	Whole lung respiratory resistance by FOT (Total Respiratory System Impedance Zrs, Resistance R & Reactance X)			C09010-01-99		
Airway Resistance	Airway respiratory resistance by occlusion technique (Rocc, $Rocc_{_{\rm EV}}$ Rocc_{_{\rm IN}} Gav, etc.)			C02700-01-11		
Integrated Dosimeter	Mannitol, metacholine bronchochallenge with integrated DeVilbiss 646 Nebulizer			C03250-01-11		
Metabolic (CPET/REE)	Cardio Pulmonary Exercise Test (VO ₂ max, Anaerobic Threshold), Indirect Cardiac Output (Wassermann), Indirect Calorimetry (REE/RMR, RQ, Energy substrate utilization)			C03254-02-11		
Safety & Quality Standards						

MDD (93/42 EEC); FDA 510(k); EN 60601-1 (safety) / EN 60601-1-2 (EMC) Complies with ATS/ERS 2005 guidelines



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