

# Innovative modularity and networking for truly customised Pulmonary Function Testing solutions





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

repeatability<sup>(1)</sup>

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

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 is needed a fully featured PFT system or a basic configuration to start a private practice.

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.

# 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 eliminats the procedure of ordinary maintenance and solve easily and rapidly 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.

(1) "ERS 2004: Lung function testing equipment: a manufacturer's unbiased viewpoint" K. Hogben, 2004 ERS Buyers' Guide to Respiratory Care Products p. 42-64



**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.

	Pneumotach (PNT)	Turbine			
Name	Х9	Turbine 2000			
Туре	Lilly type pneumotach	Bi-directional, digital			
Lifespan	Reliable through many tests	Virtually unlimited			
Flow range	0-14 l/s	0.08-20 l/s			
Ventilation range	NA	0.08-300 l/min			
Resolution	1 ml	12 ml			
Calibration	Daily (3 liters syringe)	Weekly (3 liters syringe)			
User Linearization	Yes	NA			
Flowmeter verification	Yes	Yes			
Environmental sensitivity	High, but reduced by extremely low thermal capacity to avoid condensation during expiration	Very low			
Ideal for	Body Plethysmography, Spirometry	Exercise testing			
AB Filter	Required	Required (Pulmonary Function Testing only)			
Cleaning	Disinfectant solution	Disinfectant solution			
Independent validation	For spirometry and DLCO (HRI Lab, 2012)	For spirometry (LDS Hospital, 2004)			
Eloumotors available with Quark PET and their main features					

Flowmeters available with Quark PFT and their main features

## **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 H<sub>2</sub>O).

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.

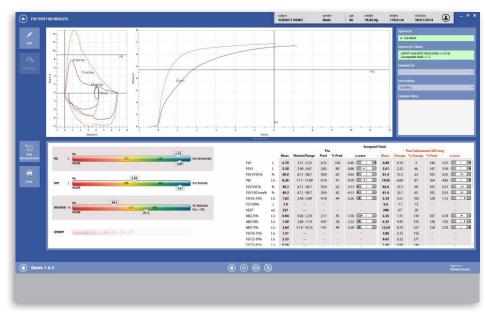
Advanced Edit function for tests/trials/captures.

Automatic interpretation statements according to measured TLC (restriction confirmed).

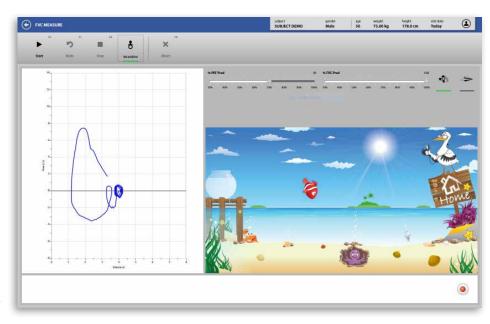
Possibility to capture multiple RAWs with one single click (up to 7).

TLC can be calculated with an Inspiratory Capacity (IC) manoeuvre other than a complete SVC manoeuvre (TLC=TGV+IC).

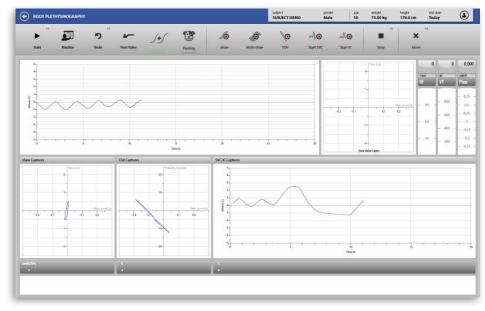
Different RAW algorithms available ( $sRaw_{TOT}$ ,  $sRaw_{ins'}$ ,  $sRaw_{exp,}$ ,  $sRaw_{0.5'}$ ,  $sRaw_{fmax}$ ).



Spirometry (FVC) review results



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



Body Plethysmography (TGV/RAW) real-time

Latest Predicteds: ERS93/ECCS, Roca/ECCS, Koch 2012, Garcia-Rio, Gutierrez (Canada).

Simulated test with optional Erlenmeyer Flask.

## **Lung Diffusing Capacity (DLCO)**

The DLCO module allows the measurement of 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<sub>4</sub> (tracer) fractions with the fastest-in-themarket NDIR analyzer.

CO analyzer designed specifically for DLCO and thus independent from exhaled CO<sub>3</sub>.

"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<sub>sb</sub> or DLCO<sub>ih</sub> 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).

Long list of available predicteds: ECCS, Crapo and Morris, Paoletti, Roca, Knudson, Gutierrez (Canada), Chhabra (India), Mary IP (Hong Kong).

# 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  $\rm O_2$  and  $\rm CO_2$  analyzers (no conventional  $\rm N_2$  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  $\rm N_2$  Wash-Out plot together with several indicators for the control of the respiratory pattern.

Quality control messages during test manoeuver (wash-out pattern).

Automatic detection of washout curve phases (N<sub>2</sub>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).

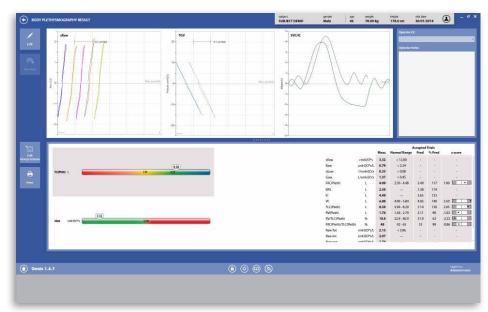
Visual leak detection by real-time FetN<sub>2</sub>

Possibility to perform SVC separately.

Latest Predicteds: ERS 93, Chhabra India, Gutierrez (Canada), Mary IP (Hong Kong), Roca, Zapletal 69.

# | CALCO SHIPS DE MACHINI MESSADT | 1/18 cm | 1

Lung Diffusing Capacity (Single breath technique)



Body Plethysmography results

# **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:

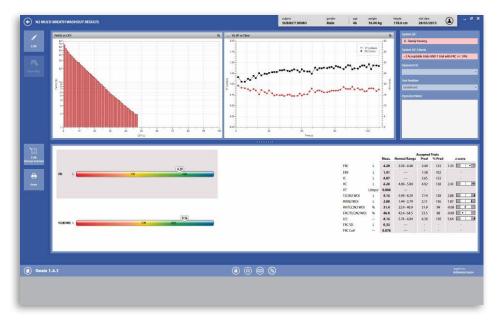
Maximal Inspiratory Pressure (MIP) and Maximal Expiratory Pressure (MEP).

Respiratory Drive assessment (P0.1)

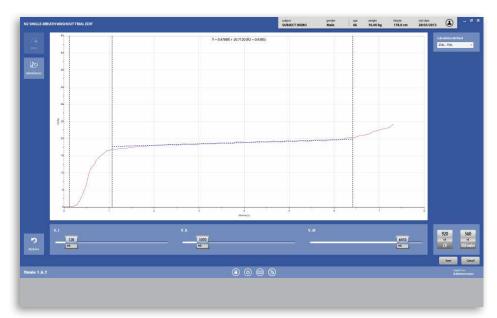
Intuitive display of all accepted maneuvers with an histogram chart (different color for Expiratory and Inspiratory maneuvers).

Compliance with 2001 ATS/ERS guidelines (one second average around peak value).

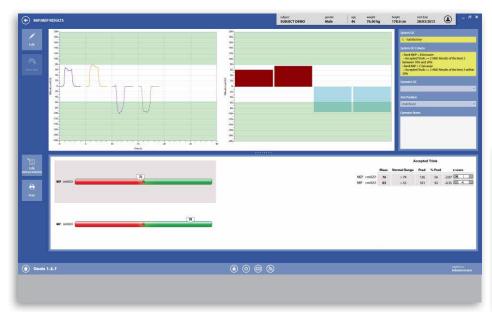
Available Predicteds: Black Hyatt, Evans, Neder.



Nitrogen Washout Multi-Breath (results)



Nitrogen Washout Single Breath (test edit)



Respiratory Mechanics MIP/MEP (results)

# **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).

Available predicteds: Asthma UK Initiative, Beydon, Lombardi, McKenzie, Merkus

# **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.

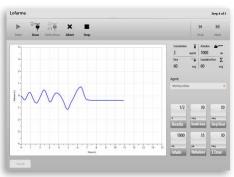
Provided with a database of standard (ATS "Five breaths" and Lofarma) and user defined protocols.

Multi-step protocol with a single drug concentration

Easy to clean and disinfect.



DeVilbiss 646 Nebulizer for integrated dosimetry tests



Dosimeter dialog box in real time

Cardio Pulmonary Exercise Test (CPET) results and post-test edit

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# 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: paramagnetic, stable and durable for the O<sub>2</sub>, rapid infrared for the CO<sub>2</sub>.

Ergonomic multi-use silicone face masks (available in 5 sizes: 3 adult, 2 pediatric) for comfortable testing in any

Independently validated on a wide range of test modes (for both exercise and resting applications) and exercise intensities.

#### **OMNIA Metabolic Software**

conditions.

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 12-lead 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 FiO<sub>2</sub> 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.

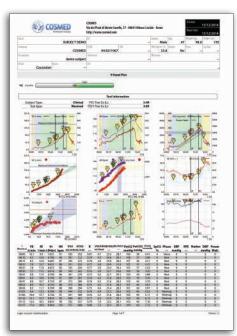
A user management system allows to define users (Physician, Technician, Administrator, etc.) and roles (which specific feature can a user access).

OMNIA can exchange data with Hospital Information Systems (HIS) via HL7, GDT and with a proprietary Protocol (OCP).

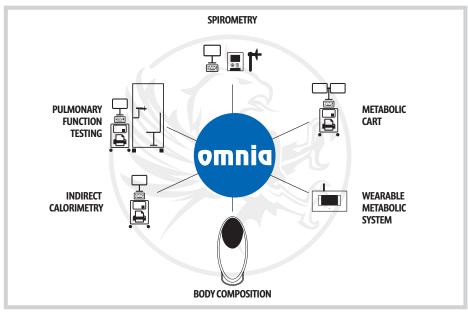
With the optional HL7 module (either standalone or network) OMNIA allows to get data from an HL7 worklist and send results back to Electronic Medical Records (EMR) and Hospital Information Systems (HIS).

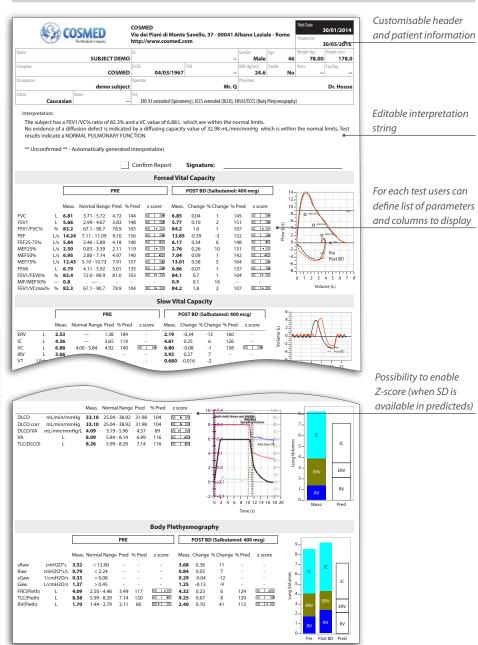
Access and security compliant according to US HipAA, ISO 27799:2008, EU 95/46/CE and 2002/58/CE.

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





Custom "PFT Summary" printout reporting with pictograms, comprehensive interpretation statements, editable charts and tabular data

#### **Spirometry**

- "ATS/ERS 2005: Standardisation of the measurement of spirometry" V. Brusasco, R.Crapo et al-Eur Respir J 2005; 26: 319–338
- "Multi-ethnic reference values for spirometry for the 3-95yr age range: the global lung function 2012 equations" Quanjer PH et al - Eur Respir J. 2012 Dec;40(6):1324-43.

#### **Bronchochallenge**

- "ERS technical standard on bronchial challenge testing" AL Coates and the Bronchoprovocation Testing Task Force. Eur Respir J. 2017 May 1;49(5).
- "ATS 1999: Guidelines for Methacholine and Exercise Challenge Testing" RO Crapo et al. Am J Respir Crit Care Med Vol 161, Pp 309-329, 2000

#### **Body Plethysmography**

- "ATS/ERS 2005: Standardisation of the measurement of lung volumes" V. Brusasco, et al - Eur Respir J 2005; 26: 511-522
- "ATS/ERS 2005: General considerations for lung function testing" V. Brusasco, R.Crapo et al - Eur Respir J 2005; 26: 153-161

#### **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)
- "ATS/ERS 2005: Standardisation of the single breath determination of carbon monoxide uptake in the lung" V. Brusasco, R.Crapo et al- Eur Respir J 2005; 26: 720-735

#### Nitrogen Washout (FRC)

- "ATS-ERS Consensus statement for inert gas washout measurement using multiple and single breath tests". Eur Respir J 2013: 41: 507–522.
- "ATS/ERS 2005: Standardisation of the measurement of lung volumes" V. Brusasco, et al - Eur Respir J 2005; 26: 511-522

#### Forced Oscillations Technique (FOT)

- "ATS/ERS2007 An Official ATS/ERS Statement: Pulmonary Function Testing in Preschool Children" - Am J Respir Crit Care Med Vol 175. pp 1304–1345, 2007.
- "ERS 2003: The FOT in clinical practice. Methodology, recommendations and future developments", Eur Respir J 2003; 22: 1026–1041

#### **Respiratory Mechanics**

 "ATS/ERS 2002: Statement on Respiratory Muscle Testing" Am J Respir Crit Care Med Vol 166. Pp 518-624, 2002

#### Metabolic

- ATS/ACCP 2003: "Statement on Cardiopulmonary Exercise Testing", American J. Respiratory Critical Care Medicine, Vol. 167. 211: 277. 2003
- ERS 2007: "Recommendations on the use of exercise testing in clinical practice", Eur Respir J 2007; 29: 185–209

# **Technical Specifications**

Product	Description			REF	
Quark PFT	Pulmonary Function Testing Laboratory			C09072-02-99	
Standard packaging	Unit, Smart Valve, Calibration Syringe (3 liters), OMNIA PC softw probes and user manual			are, adapters, cables,	
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 (		Turbine 2000 (o	optional)	
Туре	Lilly multiuse pneumotach		Bidirectional Digital Turbine ID28		
Flow Range	0-14 l/s		0.08-20 l/s		
Accuracy	±2% or 20 ml/s (flow)		$\pm$ 2% or 20 ml/s (flow) $\pm$ 2% or 200 ml/ min (ventil.)		
Resistance	<1cmH <sub>2</sub> 0/I/s @ 14 I/s		<0.6 cmH <sub>2</sub> 0 /l/s @ 14l/s		
Volume range	NA		0.08-300 l/min	0.08-300 l/min	
Gas Analyzers	0,	CO <sub>2</sub>	CO	CH₄	
Module	Metabolic, N <sub>2</sub> WO	Metabolic, N <sub>2</sub> W0	DLCO	DLCO	
Туре	Paramagnetic	NDIR	NDIR	NDIR	
Range	0-100%	0-10%	0-0.35%	0-0.35%	
Accuracy	$\pm0.1\%$	$\pm0.02\%$	$\pm0.003~\%$	$\pm0.003~\%$	
Hardware					
Dimensions & Weight	33x41x16 cm / 11 Kg				
Interface ports	USB A-B, RS-232, HR-1	ΓTL, SpO <sub>2</sub>			
Electrical requirements	100-240V ± 10% 50/60 Hz				
Environmental conditions	Temperature10-40°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				
PC Configuration	I3 or higher processor speed. Compatible with Windows 7, 8, 8.1, 10 (32 or 64 bit). RAM 4GB (8GB recommended). HD with 10GB of free space				
Optional HW Modules	Description			REF	
Body Plethysmography	Lung Volumes (TGV, TLC, FRC), Airway Resistance (RAW, sRAW, GAW, sGAW), Respiratory Mechanics (MIP/MEP, P0.1)			C03251-01-11	
Lung Diffusing Capacity				C03240-01-11	
Lung Volumes N <sub>2</sub> W0	FRC by Multi-Breath Nitrogen Wash-out, Closing Volume by $$\rm C03255\text{-}01\text{-}11$$ Single-Breath 100% $\rm O_2$				
Respiratory Mechanics	Maximum Inspiratory/Expiratory Pressure (MIP/MEP), P0.1			C03257-01-11	
Airway resistance (Rocc)	Occlusion Resistance measurement (Pre and Post Bronchodilatation)			C02700-01-11	
Forced Oscillation	Whole lung respiratory resistance by FOT (Total Respiratory System Impedance Zrs, Resistance R & Reactance X)			C09010-01-99	
Integrated Dosimeter	Mannitol, metacholine bronchochallenge with integrated DeVilbiss 646 Nebulizer			C03250-01-11	
Metabolic (CPET/REE)	Cardio Pulmonary Exercise Test (VO <sub>2</sub> 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

CE



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To know more:

Subject to alterations without prior notice. REF C09072-02-93