Quark SPIRO

Spirometry Lab

Modular Spirometry Laboratory for bronchial challenge and airways resistance tests

- Full Spirometry testing (FVC, SVC, MVV, Pre/Post BD)
- Three flowmeter configurations available: digital turbine; multi and single-use pneumotach
- Integrated dosimeter for accurate and easy bronchial challenge tests (optional)
- Wide range of options and accessories available (Airway resistance by Interrupter Technique, integrated SPO_2 monitor, etc)
- Low maintenance costs, no technical expertise required
- User friendly software and advanced features with new generation OMNIA Suite
- Meet latest ATS/ERS standards

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Quark SPIRO is a modern laboratory for complete spirometry testing, with additional sophisticated applications like integrated dosimeter and airway resistance modules. The system is fully modular and offer a choice among three different flowmeter configurations: digital turbine, multi-use pneumotach (X9) and single use pneumotach (Flowsafe). Low maintenance costs, thanks to its iInnovative "plug and play" design, make Quark Spiro the Quark PFT the perfect laboratory for accurate, frequent and reliable spirometry. The system fully complies with ATS/ ERS recommendations for respiratory functionality tests.

Testing

Spirometry

- Full Spirometry (FVC, SVC, MVV, Pre/ post BD)
- 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
- Includes latest Global Lung Initiative (GLI) predicteds (including Z-score)
- ATS, Metacholine-dose, Mannitol and user defined Bronchochallenge protocols
- Possibility to download Six Minute Walk Test data from any Spiropalm 6MWT
- Pressure control during drug delivery to ensure maximal accuracy
- Cleaning and disinfecting the nebulizer, tubing and mouthpieces are made extremely easy

Interrupter Technique (Rint/Rocc)

- Respiratory resistance (Rint, Rocc, RoccEX, RoccIN, Gav etc.)
- Dedicated low-flows pneumotach
- Not required collaboration by the patient (ideal solution for testing non-collaborative subjects and children)
- Easy to mount and to disinfect
- Antibacterial filters can be used to eliminate the risk of cross-contamination

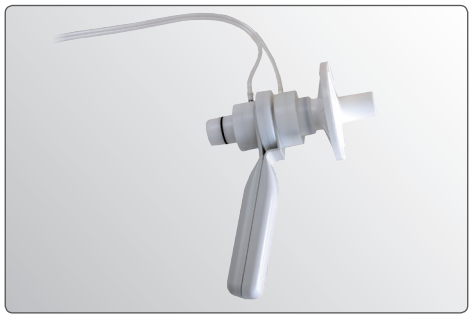
Integrated Pulse Oximeter

- Oxygen saturation (SpO2) and Heart Rate (HR) at rest and during exercise
- High quality integrated monitors (Nonin© technology)
- Available with a broad range of accurate and dependable sensors (finger, earlobe or forehead/reflectance)
- Low power draw (60 mW)
- Intelligent pulse-by-pulse filtering

Design/Hardware

- Modular design architecture eliminates the procedure of ordinary maintenance

Digital turbine



Multiuse Pneumotachograph (X9)

Integrated dosimeter for automatic broncho-challenge tests

Optional Modules

Integrated Dosimeter

- Allows controlled and more accurate management of bronchial challenge tests with an improved analysis of airways reactance
- The module provides a nebulizer, powered by dry compressed air (it is required medical air/gas for drug inhalation) and connected to the flowmeter with dedicated tubing.
- ATS/ERS based "Five breaths" predefined dosing protocol
- Possibility to add personalised dosing protocols for supplied quantities of broncho-stimulants
- Multi-step protocol with a single drug concentration

- Solve easily and rapidly any technical problem by replacing a board
- Choice among 3 different flowmeter configurations (digital turbine, multiuse pneumotach and disposable pneumotach)
- Optional medical graded cart allows easy move of Quark Spiro and accessories anywhere in your lab
- Equipment complies with MDD (93/42 EEC) and FDA 510(k)

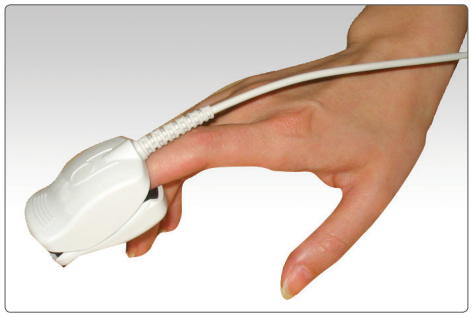
Accuracy/Reliability

- Meets ATS/ERS standards for spirometry testing
- Quality control messages according to the guidelines for spirometry tests
- Flowmeter ensures maximum precision throughout a wide range of flows (up to 20 l/s) and a very low flow resistance (less than 0.7 cm H2O/l/s at 12 l/s)
- Independent validation of turbine flowmeter by LDS Hospital using the ATS 24 standard volume-time waveforms
- Built-in temperature sensor, for the automatic correction of the results to BTPS conditions. Not influenced by heat, humidity, barometric pressure, or altitude
- Included 3L calibration syringe for flow calibration

Data Management & Software (OMNIA)

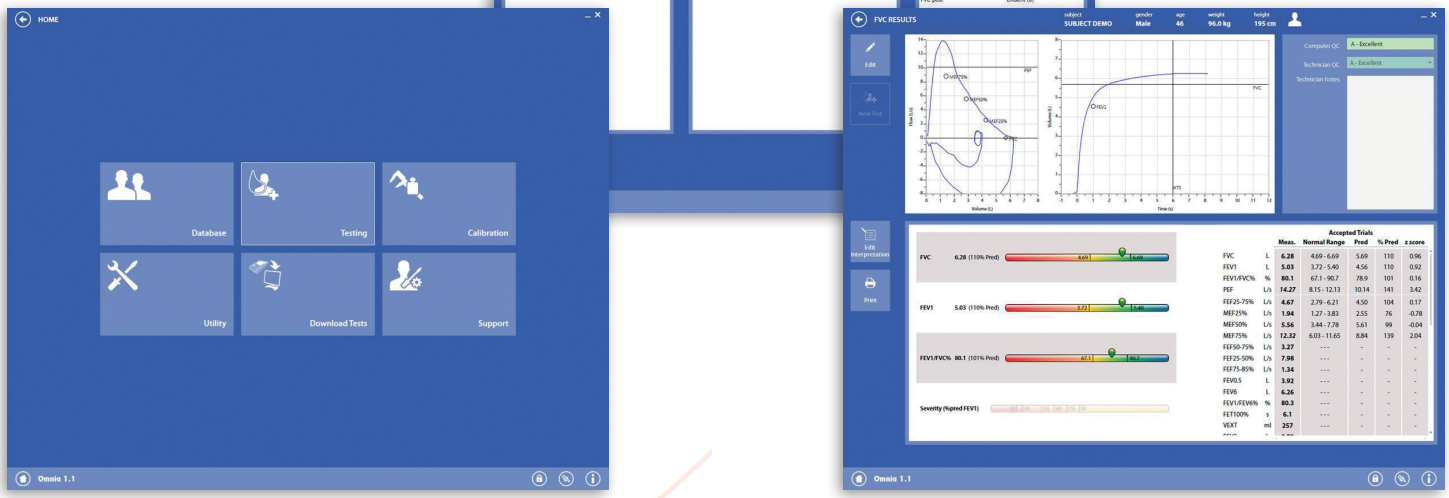
- Innovative user interface, touch screen, easy and self-explanatory
- Compatible with Win 8 PRO (32/64), Win 7 (32/64), Win Vista (32/64)
- Graphical data presentation both at screen and on printouts with gauges (pictograms)
- Quick and advanced calibration procedures for high accuracy measurements either for flowmeters (calibration and linearity check), gas sensors (zero, gain and delay) and body box (box leakage and the polytrophic factor)
- New Control Panel for easy maintenance/troubleshooting of any COSMED device
- Powerful algorithm automatically elaborating results and providing comprehensive interpretation text strings including numerical results
- Full customizable time-based trends of main measured parameters
- GDT data interface protocol included
- Access and security compliant (according to US HipAA, ISO 27799:2008, EU 95/46/CE and 2002/58/CE)
- Compatible with Windows Server 2008 (SP2, R2 SP1), Server 2012

The interrupter technique (Rocc) is highly indicated for airway resistance assessment in pediatric applications



Pulse oximeter for SpO_2 saturation measurements

Innovative pediatric incentivation with selectable effort grade.



Omnia combines power and simplicity in an innovative user interface

Technical Specification

Flowmeter	Single use Pneumotach	Multi-use Pneumotach	Digital Turbine
Type	Pressure transducer (lilly)	Pressure transducer (lilly)	Bidirectional 28 mm
Flow range	0-14 l/s	0-14 l/s	0-16 l/s
Volume range	12 litres	12 litres	12 litres
Accuracy of reading	±2% or 20 ml/s	±2% or 20 ml/s	±2% or 20 ml/s
Resistance	<1.0 $cmH_2O/l/s$ @ 14 l/s	<1.0 $cmH_2O/l/s$ @ 14 l/s	<0.6 $cmH_2O/l/s$@14l/s

Measured Parameters (partial listing)

FVC • IVC • VC • MVV • VT • FEV1 • FEV6 • FEV1/FEV6 • FEV6/FVC • PEF • PIF • FEV1/FVC • FEF 25-75 • FEV1/VC% • %FEV1 • MEF25% • MEF50% • MEF75% • FET 100% • Lung Age • ERV • IRV • VE • Rf • ti • te • ti/t.tot • VT/ti • Best FVC • Best FEV1 • IC • SpO2 • HR • R_occ • G_occ

Predicted values (partial listing)

2012 Global Lung initiative (GLI), ERS 1993 (ECCS 1983), NHANES III, Knudson 83, ECCS 1971, ITS, Zapletal, LAM, Pneumobil, Gutierrez (Chile), Multicèntrico Barcelona, Thai 2000, Austria (Forche), Crapo 1981 user defined predicted calculations.

Automatic Interpretation

ATS/ERS 2005 (Spirometry), GOLD COPD, ATS/ERS 2005 (Obstruction Reversibility based on FVC Post BD)

Hardware

Temperature	0-50 °C (32-122 °F)
Pressure	400-800 mmHg
Humidity	0-100%
Dimensions (cm)	33 x 41 x 16
Weight (kg)	6

Standard Packaging includes

Quark Spiro unit, USB cable, RS232 cable, 3L calibration syringe, PC software, user manual

Available languages

Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese, Korean, Romanian, Czech

PC configuration required

OS Compatibility	Vista (32/64), Windows 7 (32/64), Windows 8 (32/64)
Processor speed	1.4 GHz or faster
RAM	1 GB or greater
Disk space	500 MB of free disk space plus 100 MB for .NET framework plus 512 MB for SQLServer 2008 R2 SP1 Express
Monitor	Min. screen resolution 1280 x1024 pixels

Electrical requirements

Power supply	100/240V±10% 50-60 Hz
Power	100 W
Class	I type BF (IEC60601-1)

Safety and Quality Standards

Equipment complies with MDD (93/42 EEC) and FDA 510(k) cleared, EN 60601-1 (safety) and EN 60601-1-2 (EMC)
COSMED is an organisation whose quality management system is certified by CERMET according to UNI EN ISO 9001:2008 and UNI EN ISO 13484:2004

CE 0476

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