



The ultimate modular solution for bronchial challenge and airway resistance tests

- ▶ Three flowmeter configurations available: digital turbine; single use pneumotach Flowsafe; multi-use pneumotach Flowsafe X9
- ▶ Full Spirometry testing (FVC, SVC and MVV)
- ▶ Integrated dosimeter for accurate and easy bronchial challenge tests (optional)
- ▶ Airways resistance (R_{occ}) and integrated SPO₂ monitor (optional)
- ▶ Advanced software for real time management of results



Quark SPIRO is a modern laboratory for complete spirometry testing, allowing also more sophisticated applications with integrated dosimeter and airway resistance module. The system is designed in order to allow the choice of modules and options according to the specific user's needs.

The innovative design architecture eliminates the procedure of ordinary maintenance and allows to easily solve any technical problems by replacing a board.

Quark SPIRO ensures great accuracy exceeding ATS and ERS criteria.

The operating software, designed for Windows XP and compatible with VISTA, provides easy operations and functionality. User-friendly interface, intuitive commands and icons are the perfect tools for fast and reliable data collection in any hospital department or doctor office.

Applications

- ▶ Pulmonary function testing departments
- ▶ Primary care
- ▶ Occupational health
- ▶ Clinical trials

Accurate and Reliable Flow and Volume measurements

Quark Spiro is available with three different configurations:

- ▶ the bidirectional digital turbine flowmeter (that requires the use of antibacterial filters)
- ▶ the new disposable Flowsafe, a single use differential pressure transducer (that does not require antibacterial filter)
- ▶ the multi-use pneumotach Flowsafe X9, characterised by high accuracy and extremely low thermal capacity (so avoiding condensation during expiration).

All flowmeters comply with the most stringent requirements for accuracy fixed by ATS and ERS.

High modularity

Thanks to COSMED innovative technology, Quark Spiro can be upgraded with modules and options for any particular need. The system incorporates "plug and play" circuitry for instant upgrades.

Spirometry Module (standard)

Includes all necessary functions for complete spirometry tests execution (FVC, SVC, MMV and bronchial challenge test).

Dosimeter Module

Quark Spiro can be integrated with the dosimeter module for a simplified management of bronchial challenge tests and a better analysis of airways reactivity:

- ▶ Use of the "Five breaths dosimeter" ERS protocol"
- ▶ Possible personalised protocols creation for supplied quantities of broncho-stimulants
- ▶ Precise pressure control during aerosol delivery
- ▶ Functioning with compressed air (requires medical air/gas for drug inhalation).

Airways Resistance

Includes a unit for the airways resistance measurement with the occlusion technique (Roc/Rint).

Integrated SPO₂ Monitor

With this module it is possible to use finger, ear and reflectance pulse oximeter for oxygen measurements (SpO₂) at rest and during exercise.

PC Software

Quark Spiro comes with a powerful software that allows efficient management of PC data:

- ▶ Complete database management for patients, diagnosis, clinical report, bronchial challenge protocols;
- ▶ User defined protocols to easily manage bronchial challenge tests;
- ▶ Detailed printing of F/V, V/t, bronchial challenge response graphics, PD 10, 15 and PD 20 calculation;
- ▶ Pre-Post test with either bronchial dilator or metacholine;
- ▶ Powerful post-analysis elaboration of data with possibility to compare tests performed in different test sessions;
- ▶ Multiple parameters trend analysis;
- ▶ Software encouragement tool for children and non-cooperative patients;
- ▶ Several selectable sets of predicted values;



Turbine flowmeter



"Flowsafe", single use pneumotach



Pulse oximeter for SpO₂ saturation measurements



Integrated dosimeter for automatic broncho-challenge tests

Bronchial challenge Test

Users can execute a pre/post test after the assumption of a broncho stimulant and following defined protocols to easily manage bronchial challenge/dilator tests.

Airways Resistance

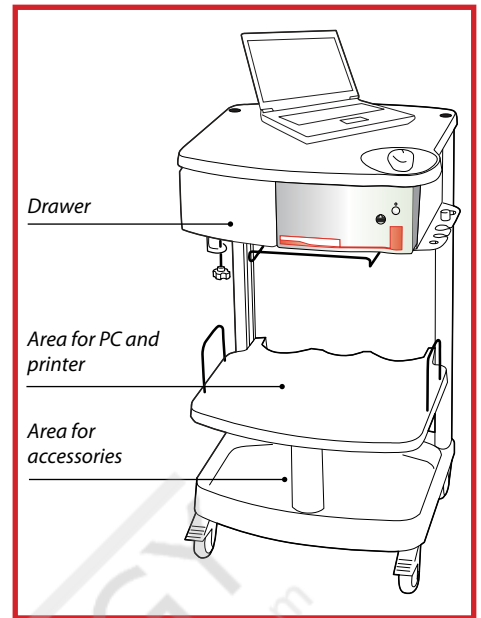
Respiratory resistance is calculated with interrupter technique. The shutter is closed during 100ms at the begin of the exhalation and is totally imperceptible for the patient. The Rocc kit brings accurate airways resistance measurements, highly indicated for paediatric applications.

Automatic diagnosis

The automatic interpretation of test results as per the latest interpretation criteria fixed by ATS and ERS, is automatically suggested by the software at the end of the test. User however can manually modify the diagnosis, customize the diagnosis database and add notes. Pony FX is currently the unique spirometer that incorporates the diagnosis for COPD after a broncodilator test.

Post data elaboration

Powerful post-analysis data elaboration with possibility to overlap tests performed in different test sessions. Multiple parameters trend analysis.



New medical cart with isolation patient transformer required for medical environments.

- ▶ Create custom parameters and user defined set of predicted equations;
- ▶ New NHANES III predicted equations included;
- ▶ Printout report according to the ERS-ATS requirements;
- ▶ Customizable printouts as per user's requirements;
- ▶ Best Test selection and results reproducibility according to ATS 1994 standards;
- ▶ Quality control messages according to the ATS guidelines for spirometry tests.

The image displays several screenshots of the software interface. The top right shows a 'New Respiratory Challenge' dialog box with fields for 'Inhaler', 'Accepted pressure', and 'Respiratory Challenge' parameters. Below it is a 'Parameter List' table with columns for Parameter, Unit, Pred., ES1/F1, and SP/PA. The middle left shows a graph of 'Forced Vital Capacity' with multiple curves. The middle right shows a 'Response to Beta2-agonist' graph. The bottom right shows a detailed 'Parameter List' table with columns for Parameter, Unit, Pred., ES1/F1, SP/PA, PC1/F1, PC2/F1, and PC3/F1. The bottom left shows a cartoon illustration of two children blowing into balloons.

Parameter	Unit	Pred.	ES1/F1	SP/PA
FVC	liters	6.78	0.82	185.8
FEV1	liters	5.75	0.75	158.9
FEV2	liters	5.15	0.68	138.9
FEV3	liters	4.75	0.62	128.9
FVC	liters	5.78	0.78	175.8
FEV1	liters	4.75	0.75	158.9
FEV2	liters	4.15	0.68	138.9
FEV3	liters	3.75	0.62	128.9
FVC	liters	5.78	0.78	175.8
FEV1	liters	4.75	0.75	158.9
FEV2	liters	4.15	0.68	138.9
FEV3	liters	3.75	0.62	128.9

Real time graphic and numeric visualization of spirometry tests

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 ₂ O/l/s @ 14 l/s	<1.0 cmH ₂ O/l/s @ 14 l/s	<0.6 cmH ₂ O/l/s@14l/s

Measured Parameters

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

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.

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, PC software, user manual. The standard packaging is implemented for each module with a specific kit.

Available languages

English, Italian, French, German, Spanish, Portuguese, Turkish, Chinese (Mandarin), Korean.

PC configuration

PC Pentium or above, Windows XP, VISTA 32, 128 Mb RAM or above, USB port, CD-Rom reader, 80 Mb available space on HD, Monitor VGA, SVGA, XGA, mouse and printer compatible with MS Windows operating system.

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



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