

**NEW**



The first and unique solution combining Spirometry and advanced Six-Minute Walk Test

- ▶ Real-time testing for the standard 6MWT (Six-Minute Walk Test)
- ▶ Measurement of minute Ventilation (VE) and Breathing Pattern during walking, Breathing Reserve (BR) with Ventilation Limitation statement
- ▶ HR and SpO<sub>2</sub> Monitoring by Nonin®
- ▶ Evaluation of Dynamic Hyperinflation, with the measurement of Inspiratory Capacity (IC)
- ▶ USB connection for external Printer and PC software for data management



Spiropalm 6MWT is a new medical device designed by COSMED incorporating the latest design for portable spirometry and a unique tool for the standardized "Six-Minute Walk Test"(6MWT). The versatility of the Spiropalm 6MWT allows a new way of measuring and reporting results for the Six-Minute Walk Test. No more clipboards, stopwatches, lap counters or non integrated pulse oximeters. The Spiropalm 6MWT provides the customer with a complete testing package with an integrated pulse oximeter, along with the ability to measure ventilation during the test. With the integration of the pulse oximeter the technician will be able to monitor SpO<sub>2</sub> during the Six-Minute Walk Test, but also to provide a complete O<sub>2</sub> saturation report for oxygen prescription.

Measuring ventilation is important clinical information as technicians will be able to assess ventilatory limitation. Spiropalm 6MWT also allows to measure and evaluate hyperinflation and airtrapping in patients with pulmonary disease.

With limited investment, Spiropalm 6MWT performs an integrated evaluation of the cardiovascular, respiratory and muscular adaptation during walking (and also during other exercise performances).

Spiropalm 6MWT fully complies with requirements from "ATS/ERS Guidelines for the Six-Minute Walk Test" (2002).

- ▶ Integrated pulse oximeter (Nonin®) for oxygen saturation (SpO<sub>2</sub>) and HR monitoring.
- ▶ For comfortable test execution, the Spiropalm 6MWT is tied at patient's waist level through an elastic belt plus a holder. Alternatively, the holder can be hooked up directly to the patient's trousers. The particular design of the holder allows tidy wrapping of cables.

1Test 2Print 3Diagn. 4Disp.BC 5Erase 0Exit			
Six Minute 09/04/09	Param	Meas	Pred
	Distance(m)	294	492
	DYSPNEA end	6	
	FATIGUE end	4	
	End SpO2(%)	94	
	Min SpO2(%)	92	
	Final SpO2(%)	96	
	Max VE(l/min)	29.6	
	BR(%)	20.0	
	Max HR(1/min)	66	

Spiropalm screenshot: end of 6MWT

## 6MWT Parameters

### Before test:

- ▶ FEV1
- ▶ Dyspnea baseline (Borg scale)
- ▶ Fatigue baseline (Borg scale)
- ▶ SBp (mmHg)
- ▶ DBp (mmHg)
- ▶ Supplemental Oxygen
- ▶ O<sub>2</sub> Flow (L/min)
- ▶ Test duration (min)



### During test:

- ▶ Elapsed Time (mm:ss)
- ▶ SpO<sub>2</sub> (%)
- ▶ Heart Rate HR (1/min)
- ▶ Ventilation VE (l/min)
- ▶ Respiratory Frequency RF (1/min)
- ▶ Dynamic Inspiratory Capacity IC (l)

### End of test:

- ▶ Walk Distance (m)
- ▶ Dyspnea & Fatigue End
- ▶ Symptoms

## Applications

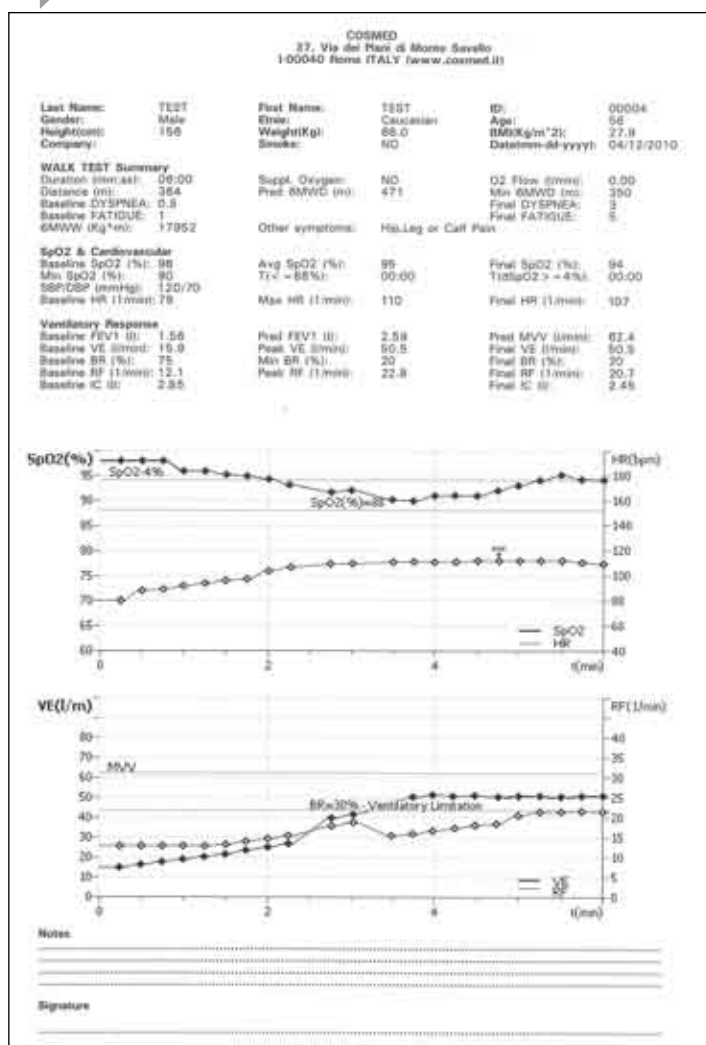
- ▶ Hospitals: RT Departments, PFT labs, Allergy Clinic
- ▶ Physician: Allergist, Primary Care, Pulmonary, Pediatric Pulmonologist
- ▶ Pulmonary Rehabilitation
- ▶ Allied Health Education, RT, PT, Nursing

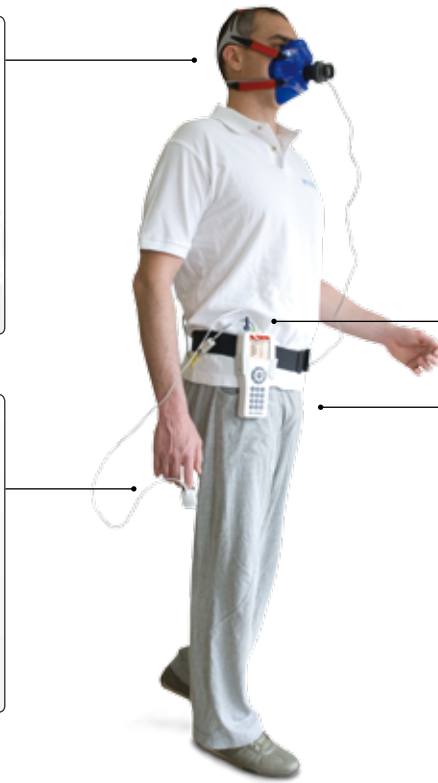
## 6MWT Characteristics

Spiropalm 6MWT includes:

- ▶ Turbine flowmeter, connected to a silicone face mask with head cap for measurement of ventilatory parameters

Spiropalm 6MWT allows to print reports with compatible printers via direct USB connection. Reports can also be saved in PDF format by a configured USB stick.





1.BaseLine 2.Start Walk 3.Min 4.IC 5.End 0.Exit	
Time (mm:ss)	05:17
SpO2(%)	98
HR(1/min)	95
VE(L/min)	24.7
RF(1/min)	21.3
IC(L)	1.0



## Including Full Spirometry

Spiropalm 6MWT also allows the possibility to perform standard spirometry testing:

- ▶ Slow/Forced Vital Capacity (SVC/FVC)
- ▶ Maximal Voluntary Ventilation (MVV)
- ▶ Bronchial challenge test (Pre-Post)

## PC Software (Spirometry only)

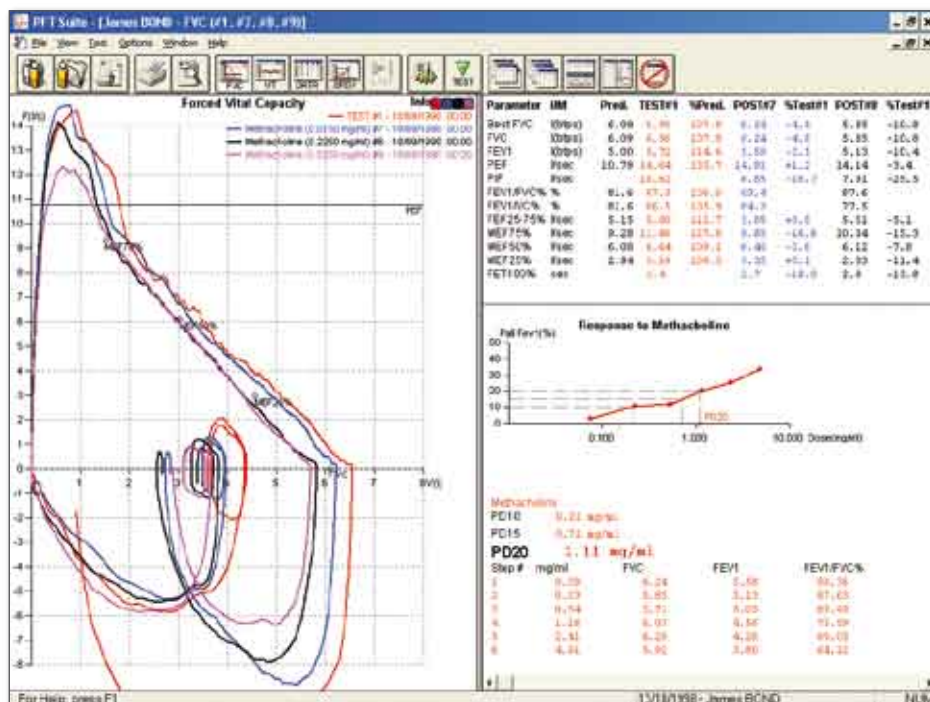
User-friendly software allows spirometry testing via USB interface and data download for results management through simple, intuitive commands and icons.

The software contains advanced features and user defined protocols to easily manage bronchial challenge tests.

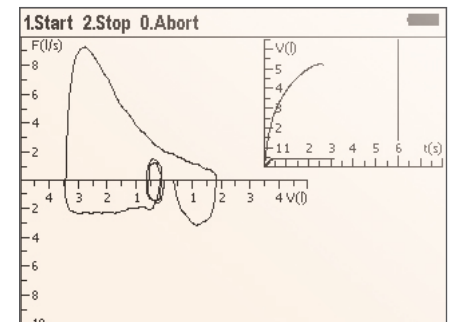
The ability to compare tests performed in different sessions is available.

Test	
1	FVC
2	FVC post BD
3	FVC post BC
4	SVC
5	MVV
6	SPO2
7	Walking Test

Spiropalm Screenshot: list of spirometry tests



PC software allows real time graphic and numeric visualization of spirometry tests



Spiropalm Screenshot: graphical representation during spirometry testing

1.Start 2.Save & Exit 3.Curve 0.Exit					
F(I)	Param	Meas	Pred	%	
1	#1BEST	FVC	5.29	4.88	108
	FEV1	3.95	3.97	99	
2	#2LAST	FVC	4.91	4.88	100
	FEV1	3.75	3.97	94	
3	FVC	4.86	4.88	99	
	FEV1	3.75	3.97	94	

Spiropalm Screenshot: spirometry results



Possibility to save PDF reports directly in the USB pen drive

#### 6MWT References:

- "ATS Statement: Guidelines for the Six-Minute Walk Test." American Journal of Respiratory and Critical Care Medicine Vol 166. pp. 111-117, (2002).
- Enright PL, Sherrill DL. "Reference equations for the six-minute walk in healthy adults." AM J RESPIR CRIT CARE MED 1998;158:1384-1387.
- T. Troosters, R. Gosselink, M. Decramer "Six minute walking distance in healthy elderly subjects." Eur Respir J 1999; 14: 270±274.

#### Spirometry References:

- ERS 1993 (ECCS 1983), NHANES III, Knudson 83, ECCS 1971, ITS, Zapletal, LAM, Pneumobil, Gutierrez (Chile), Multicentrico, Barcelona, Thai 2000, Austria (Forche), Crapo 1981.

## Technical Specification

### Products Features

Flowmeter	Digital Turbine
Type	Bidirectional
Flow Range	0.08-20l/s
Volume range	12 litres
Accuracy of reading	±2%
Resistance	<0.6 cm H <sub>2</sub> O/l/s @ 14 l/s
Temperature sensor	0-50°C

### Measured Parameters

#### 6MWT Parameters:

Distance (m), 6MWW (Kg\*m), SpO<sub>2</sub>(%), HR (%), T88 (≤88%) (mm:ss), T (ΔSpO<sub>2</sub> ≥ 4%) (mm:ss), VE (L/min), RF (1/min), BR (%), IC (L), SBp (mmHg), DBp (mmHg), Borg Dyspnea (x.x), Borg Fatigue (x.x).

#### Spirometry 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 • SpO<sub>2</sub> • HR

### Hardware

Dimension (mm/in)	185x86x31/7/4 x 3 1/4 x 1 1/4
Weight (gr/oz)	390/13½
Display	LCD B/W 320 x 240 pixel (amber backlighted)
Internal memory	of up to 1000 tests/patients
Calibration	3L Calibration Syringe (option)
Recording time	2-30 minutes

### Direct USB Printing

Only with compatible HP PCL printers with an USB port for data transmission.

### Standard Packaging Includes

PC software and user manual, Flowmeter, AC/DC adapter (110-240V), USB communication cable, Carrying case, Pediatric mouthpiece adapter, Mouthpieces and nose clips, Anti-Bacterial filters. CD-Rom, 6MWT Kit (pulse oximeter Nonin, silicon face mask, headcap, elastic belt and product holder), USB key storage

### Available languages

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

### PC configuration required

Pentium or faster. Operating system: Windows XP, 2000, 98/95, NT, Vista (32 bit), Windows 7 (32 bit). 32 Mb RAM or more, Available USB port, CD-ROM Drive, 20 Mb on HD space available, Monitor VGA, SVGA, XGA, Any mouse and printer compatible with the MS Windows™ operating system

### Electrical requirements

Internal batteries	Rechargeable Li-Ion 1800mAh
Battery Charger	Input 100-240Vac 200mA, Output 12Vdc 700mA)

### Safety & Quality Standards

Equipment complies with MDD (93/42 EEC);  
EN 60601-1 (safety) / EN 60601-1-2 (EMC).



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