

Spiropalm 6MWT

Hand-held Spirometer

Bed-side spirometer with advanced Six Minute Walk Test

“Effective, simple lung screening in any environment”



COSMED
The Metabolic Company

“

Oxygen desaturation and minute ventilation assessment during the Six Minute Walk Test (6MWT) may improve functional status evaluation⁽¹⁾”



- Exercise capacity, oxygen saturation and minute ventilation (VE) during the 6MWT
- Inspiratory capacity measurement for dynamic hyperinflation assessment
- Integrated Nonin[®] SpO₂ monitor
- Full spirometry testing (FVC, SVC, MVV, Pre-Post BD)
- Provided with OMNIA software for data management, real time testing and interpretation on PC



Spiropalm 6MWT is an innovative medical device incorporating the latest design for portable spirometry and a unique tool for the standardized Six-Minute Walk Test (6MWT).

Spiropalm 6MWT provides the customer with a complete testing package with the ability to measure minute ventilation and breathing pattern during walking together with a fully integrated pulse oximeter to monitor SpO₂ and HR during the test. Spiropalm 6MWT allows thus a full assessment of ventilation limitation due to dynamic hyperinflation and air trapping in patients with pulmonary disease.

Spiropalm 6MWT was awarded with the 2013 ERS “Product of Outstanding Interest” (POINT) Award. Its versatility was recognised as “a new way of measuring and reporting results for the Six Minute Walk Test (6MWT) by evaluating exercise capacity with integrated pulse oximeter and ventilation measurement”.

Design

- **Enhanced 6MWT** Turbine flowmeter, connected to a silicone face mask with head cap for measurement of ventilatory parameters. Oxygen saturation monitored by an integrated pulse oximeter (Nonin[®]).

- **Truly hand-held device:** compact size and light weight (only 390 gr). Internal memory that can store up to 600 tests/patients. Li-Ion battery with autonomy of up to 6 hours (charging time 2h10).
- **High accuracy:** Meets ATS/ERS standards for spirometry (2005) and 6MWT (2002) testing. Independent validation of the turbine flowmeter by LDS Hospital using the ATS 24 standard volume-time waveforms.
- **USB port** for download data in OMNIA and for real-time spirometry testing.

Six Minute Walk Test (6MWT)

- Measurement of minute ventilation (VE) and breathing pattern (Rf) during walking.
- Integrated oxygen saturation and HR monitoring during walking.
- Real time visualization of main 6MWT parameters on the Spiropalm LCD.
- At end of test, manually enter Six Minute Walk Distance (6MWD) and Borg dyspnea and fatigue levels.
- Breathing Reserve (BR) with ventilation limitation statement.

- Dynamic Hyperinflation evaluation through Inspiratory Capacity (IC) changes from baseline.
- Printout fully compliant with ATS/ERS guidelines for 6MWT (2002).

Spirometry

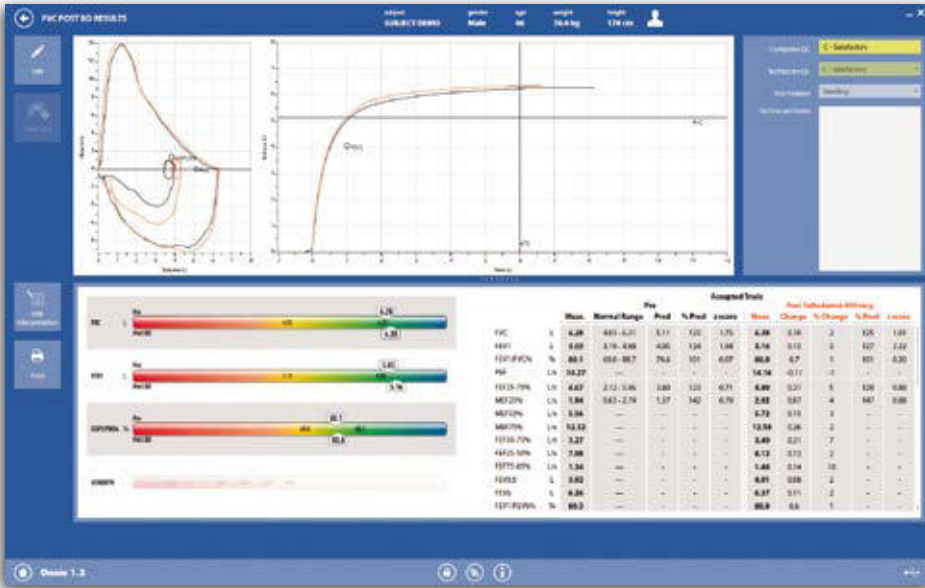
- Full spirometry testing (FVC, SVC, MVV, Pre/post BD).
- Available two test modes: either stand-alone with the Spiropalm unit and then download on PC or performed test in real time using directly the software interface.

Data Management & Software

- Innovative user interface, touch screen, easy and self-explanatory
- Compatible with Windows 10
- Graphical data presentation both at screen and on printouts with gauges (pictograms)
- Powerful algorithm automatically elaborating results and providing comprehensive interpretation text strings including numerical results
- Full customizable time-based trends of main measured parameters

(1) Bystrov V. et al 2013 “The six-minute walking test accompanied by pulse oximetry and ventilation assessment in patients with pulmonary arterial hypertension”

- New trial selection and quality control functions (in compliance with ATS/ERS guidelines).
- Innovative pediatric incentivation software with user-defined effort grade on both PEF and FVC predicted.
- ATS, Metacholine-dose, Mannitol and user defined Broncho-Provocation protocols.
- Includes new standards and predicted according to latest guidelines for spirometry (2005 ATS/ERS Consensus, GLI, GOLD COPD Interpretation).
- New calibration procedures (calibration and linearity check) according to latest Occupational Health standards.
- Intuitive 6MWD gauge featuring measured vs predicted distance.
- Edit function allows to eventually delete single steps ("invalid breath") in the 6MWT.



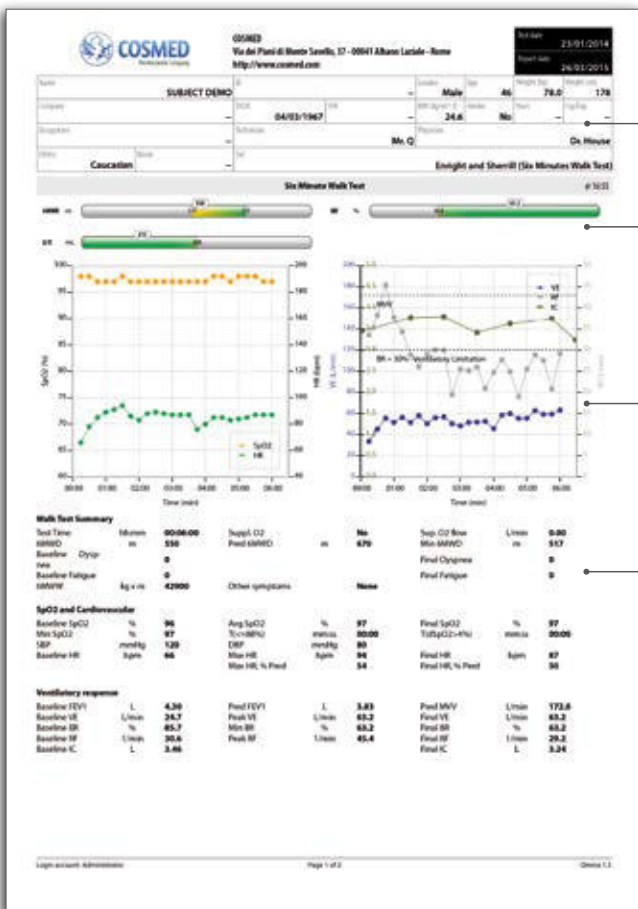
Spirometry tests can be performed directly on a PC with OMNIA, the new software generation from COSMED

1.BaseLine	2.Start Walk	3.Mrk	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				

Spiropalm screenshot: during the 6MWT

X.Cancel OK.Confirm	
WalkDistance (m)	
DISPNEA end	N/A
FATIGUE end	N/A
Other symptoms	None

Entering 6MWD and Fatigue levels after the test



Customisable header and patient info

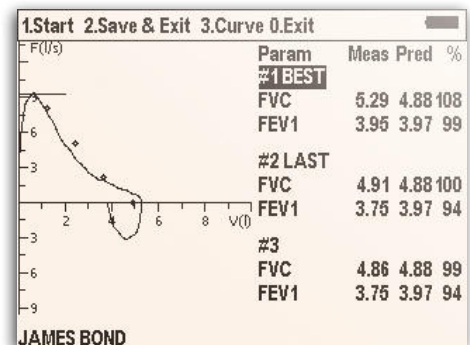
Pictograms: measured vs predicted values

Graphical representation of SpO₂/HR and VE/RF curves during the test

Measured parameters

1.Test	2.Print	3.Diagn.	4.Disp.BC	5.Erase	0.Exit
FVC	16/03/10				
Six Minute	17/03/10				
Param	Meas	Pred			
Distance(m)	385				
DYSPNEA end	1				
FATIGUE end	1				
BL SpO2(%)	98				
Min SpO2(%)	94				
Final SpO2(%)	98				
Max VE(l/min)	38				
BR(%)	40.0				
Max HR(1/min)	85				

Spiropalm screenshot: end of 6MWT



Spiropalm Screenshot: spirometry results

6MWT tests can be downloaded via USB on OMNIA software for advanced management, analysis and printing of results. Alternatively tests can also be printed directly with compatible printers connected via USB port

Validation articles

- Ponomareva I. et al. "Assessment of parameters of lung ventilation during 6-minute walk test in patients with COPD"
- Bernardi E. et al 2015 "Ventilatory analysis during 6MWT gives relevant information about exercise limitation in COPD"
- Bocchino M. et al 2014 "6MWT performance by means of Spiropalm in patients affected by fibrotic idiopathic interstitial pneumonias: Preliminary observations"
- Piaggi G. et al 2013 "Analysis of ventilation profile during six minutes walking test"
- Bystrov V. et al 2013 "The six-minute walking test accompanied by pulse oximetry and ventilation assessment in patients with pulmonary arterial hypertension"
- Crapo R. O. (LDS Hospital) 2004 "Validation of COSMED turbine vs ATS 24 standard volume-time waveforms"
- More scientific studies on www.cosmed.com/bibliography

Technical Specifications

Product	Description	REF
Spiropalm 6MWT	Handheld Spirometer and Six Minute Walk Test	C09064-03-99
Standard packaging	Main Unit, ID28 turbine flowmeter, flowmeter handle, paper mouthpieces (adult 10pcs, pediatric 5 pcs), pediatric adapter, antibacterial filters (10 pcs), nose clips (2 pcs), AC/DC adapter, USB cable, 6MWT kit (carrying case, pulse oximeter, silicone face mask M size, headcap, elastic belt and product holder), PC software (OMNIA) and user manual.	
Standard Tests		
Tests	6MWT: Ventilation (VE), Respiratory Frequency (RF), Dynamic Inspiratory Capacity (IC), Dyspnea & Fatigue (Borg Scale), Breathing Reserve (BR), Oxygen Saturation (SpO ₂), Heart Rate (HR) Spirometry: Forced Vital Capacity (FVC) Pre/Post, Slow Vital Capacity (SVC) Pre/Post, Maximum Voluntary Ventilation (MVV), Bronchochallenge - Bronchial Dilator/Constrictor test	
Measured Parameters (partial listing)	6MWT: Distance (m), 6MWW (Kg*m), SpO ₂ (%), HR (%), T88 (≤88%) (mm:ss), T (ΔSpO ₂ ≥ 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: 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	
Predicted Values (partial listing)	6MWT: Enright and Sherrill, Troosters, Gibbons, Camarri, Chetta 6MWT Spirometry: 2012 Global Lung initiative (GLI), ERS 1993 (ECCS 1983), NHANES III, Knudson 83, ECCS 1971, ITS, Zapletal, LAM, Pneumobil, Gutierrez (Chile), Multicentrico 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), ATS/ERS 2007 (Obstruction Reversibility based on Rocc)	
Hardware		
Dimensions & Weight	185x86x31 cm / 390 gr	
Interfaces	USB-A, USB-B (external printer)	
Display	LCD B/W 320 x 240 pixel (amber backlighted)	
Batteries	1 Rechargeable Li-ion battery (1800 mAh)	
Power supply	100-240V ± 10% 50/60 Hz	
Internal memory	up to 1000 tests/patients	
Recording time (6MWT)	2-30 minutes	
Flowmeter		
Type	Turbine Ø-28mm	
Type	Bidirectional Digital Turbine	
Resolution	12 ml	
Ventilation Range	0-300 l/min	
Flow Range	0-16 l/s	
Accuracy	± 2% or 20 ml/s	
Resistance	<0.8 cmH ₂ O /l/s @ 14l/s	
Software		
Available languages	OMNIA Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese (Traditional), Chinese (Simplified), Korean, Romanian, Czech, Norwegian	
Required 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 4GB of free space (plus tools)	
Options & Accessories		
Calibration syringe	Description	REF
Calibration syringe	3L syringe for accuracy check of flow volume measurements	C00600-01-11
Consumables		
Antibacterial filters	Description	REF
Antibacterial filters	Single-use filters to prevent bacterial and viral cross contamination (box contains 50 pcs)	A-182-300-004
Nose clips	Clips for performing spirometry tests (100 pcs)	C04451-01-98
Paper mouthpieces	For spirometry testing (box contains 500 pcs)	C01805-01-98 (adult) C01814-01-98 (pediatric)
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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