Spiropalm 6MWT

Hand-held Spirometer

Bed-side spirometer with advanced Six Minute Walk Test





66 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[®] Sp02 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-lon 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 standalone 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 predicteds. ATS, Metacholine-dose, Mannitol and user defined Broncho-Provocation protocols.

Includes new standards and predicteds 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.

1.BaseLine 2.Inizio 3.Mrk 4.IC	5.Fine 0.Esci	
Time (mm:ss)	00:01	
Sp02(%)	98	
HR(1/min)	81	
VE(I/min)	5.2	
RF(1/min)	10.7	
IC(I)	0.0	

Spiropalm screenshot: during the 6MWT

WalkDistance (m)		
DISPNEA end	N/A	4>
FATIGUE end	N/A	4>
Other symptoms	None	•



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



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

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

Spiropalm screenshot: end of 6MWT



Spiropalm Screenshot: spirometry results

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 limita tion 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 <u>www.cosmed.com/bibliography</u>

Technical Specifications

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Product	Description	REF		
Spiropalm 6MWT	Handheld Spirometer and Six Minute Walk Test	C09064-03-99		
Standard packaging	Main Unit, ID28 turbine flowmeter, flowmeter handle, 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 (ΔSpO2 ≥ 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), Multicèntrico Barcelona, Thai 2000, Austria (Forche), Crapo 1981 user defined predicted calculations.			
Automatic	ATS/ERS 2005 (Spirometry), GOLD COPD, ATS/ERS 2005 (Obstructi			
Interpretation	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	$100-240V \pm 10\% 50/60 \text{ Hz}$			
Internal memory	up to 1000 tests/patients			
Recording time (6MWT)	2-30 minutes			
Flowmeter	Turbine Ø-28mm			
Туре	Bidirectional Digital Turbine			
Resolution	12 ml			
Ventilation Range	0-300 l/min			
Flow Range	0-16 l/s			
Accuracy	\pm 2% or 20 ml/s			
Resistance	<0.8 cmH ₂ 0 /I/s @ 14I/s			
Software	OMNIA			
Available languages	Italian, English, Spanish, French, German, Portuguese, Greek, Dutch, Turkish, Russian, Chinese (Traditional), Chinese (Simplified), Korean, Romanian, Czech, Norwegian			
Required PC	13 or higher processor speed. Compatible with Windows 7, 8, 8.1, 10 (32 or 64 bit). RAM 4GB			
Configuration	(8GB recommended). HD with 4GB of free space (plus tools)			
Options & Accessories	Description	REF		
Calibration syringe	3L syringe for accuracy check of flow volume measurements	C00600-01-11		
Consumables	Description	REF		
Antibacterial filters	Single-use filters with round mouthpiece (box contains 50 pcs) Single-use filters with oval mouthpiece (box contains 50 pcs)	A-182-300-004 A-182-300-005		
Nose clips	Clips for performing spirometry tests (100 pcs)	C04451-01-98		
Safety & Quality Standar	ds			
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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