Hand-held Spirometer

Bed-side spirometer with advanced Six Minute Walk Test

"Effective, simple lung screening in any environment."
Oxygen desaturation and minute ventilation assessment during the Six Minute Walk Test (6MWT) may improve functional status evaluation (1).

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 SpO\textsubscript{2} 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\textsuperscript{®}).
- **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.

**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.

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 values 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.

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.

Spirometry screenshot: spirometry results

Spirometry screenshot: end of 6MWT

Spirometry screenshot: during the 6MWT
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”
- Piaggi G. 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

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Standard packaging

- Main Unit, ID28 turbine flowmeter, flowmeter handle, paper mouthpieces (adult 10pcs, pediatric 5pcs), nose clips (2pcs), 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 (SpO2), Heart Rate (HR)
- Spirometry: Forced Vital Capacity (FVC) Pre/Post, Slow Vital Capacity (SVC) Pre/Post, Maximum Voluntary Ventilation (MVV), Bronchialchallenge - Bronchial Dilator/Constrictor test

Measured Parameters

- (partial listing)
  - 6MWT: Distance (m), 6MWW (Kg*m), SpO2 (%), 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 • FEF25-75 • FEV1/VC % • %FEV1 • MEF25% • MEF50% • MEF75% • FET 100% • Lung Age • ERV • IRV • VE • FF • RR • VT % • TV % • Best FVC • Best IC

Predicted Values

- (partial listing)
  - 6MWT: Enright and Sherrill, Troosters, Gibbons, Camarri, Chetta 6MWT

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 Roc).

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: 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 cmH2O /l/s @ 14l/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: 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 3L syringe for accuracy check of flow volume measurements | REF C00600-01-11
- Consumables: Description | REF
- Antibacterial filters: Single-use filters to 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

To know more: 0476