ADVANCED

SPIRODOC®

Handheld, Stand-alone and PC-based Spirometer

Touchscreen Spirometer and 3D Oximeter: 6MWT, Sleep Test, 24h SpO2 Holter.

Two International Patents: Design Copywrite and Multifunctional capabilities.







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MAIN features



REAL-TIME TEST

Spirometry: FVC, VC, IVC, MVV, PRE/POST Bronchodilator comparison 3D Oximetry (optional): Spot test (SpO2, Pulse), 6MWT, Sleep Test, 24h SpO2 Holter Test.

CARRY EVERYWHERE

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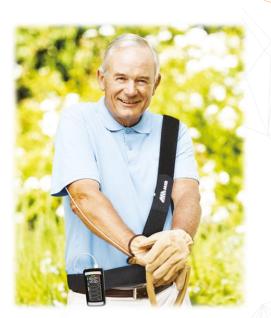
LCD Touchscreen Display, long battery life, large internal storage, carrying case included

PC CONNECTION AVAILABLE

Real-time test on PC screen, connect with your EHR/EMR, back-up internal memory and more, via USB and Bluetooth

COMPLIANCE ATS/ERS 2019

And other Standards including ISO 26782 (for Spirometry), ISO 23747 (for PEF), ISO 80601-2-61 (for Oximetry), and more. CE0476, FDA 510 (K)



DISTINCTIVE features



PREDICTED SETS & VALUES

Large Selection, including comparison %Pred, Z-score and LLN. Include GLI in PC-mode

6MWT, SLEEP TES, HOLTER

With Oximetry option, measure desaturation events during exercise, sleep and daily activities

EHR/EMR CONNECTIVITY

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Via PC, integration with patient database on your EHR/EMR (in HL7, GDT)



COVID-19 PREVENTION

Complete Disposable Set with Antiviral filter. Bluetooth connection to test at safety distance

Always INCLUDED

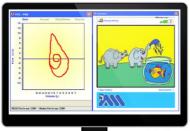
- Carrying case
- ♦ USB cable
- Noseclip
- PC Software license

With Oximetry Option:

- 📏 Finger Probe
- Plastic hard case and belt

Compatible SOFTWARE

♥ winspiroPRO



Pediatric Incentive (PATENTED) to improve patient compliance during the test.

Acceptabilty Messages, Test interpretation and Quality Control Grade according to the latest Spirometry Standards

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MAIN FEATURES

Windows-based solution for Spirometry, Oximetry and Telemedicine.

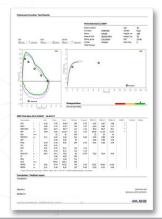
Wide range of predicted sets and values, including GLI Predicted sets, LLN and Z-score.

Embedded EHR/EMR connectivity.

NET VERSION available, share one database between different PC workstations.

MEDICAL REPORT

Specialized and customizable printout



MAIN FEATURES

Windows-based solution, direct integration with your EHR/EMR.

Real time test include Spirometry and Oximetry

Standardized communication in HL7 or Exchange Protocol. Select patient info directly from your own EHR/EMR

Spirometry test: FVC-Pre, FVC-Post, VC-Pre Oximetry Test: SpO2 (%), Pulse (BPM)

GO-TO-MARKET TOOLKIT

Software Development Kit available for System Integrators and App Developers. OEM service available for Spirometry and Oximetry.

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Learn more about available SDK and OEM



Compatible TURBINES

		Mouthpiece	Turbine Disinfection	Turbine Calibration	Packaging	Antiviral Filter
<mark>flowMIR</mark> ™ Disposable Turbine	Image: state of the state o	Included Disposable	Not required	Not required	Individually sealed: 60 or 10 units / box	Available Disposable
<mark>Reusable</mark> Turbine		Required Not Included	Required	Required	1 unit in Carton box	Required Disposable



TECHNICAL datasheet

PRODUCT CODES - Spirodoc Configurations

910600E0 – Spirometer • 910600E1 – Spirometer with reusable turbine 910610E0 - Spirometer + Oximeter • 910610E1 - Spirometer + Oximeter with reusable turbine

Technical specification			Spirometry			
Main body Width Length Fhickness Weight Furbine housing Width	dth48 mmngth101 mmckness16 mmeight99 g (battery pack included)rbine housingdth47 mmngth46 mmckness24 mm		Flow sensor Flow range Volume accuracy Flow accuracy Dynamic resistance Temperature sensor Measured parameters	bi-directional digital turbine ±16L/s ±2.5% or 50mL ±5% or 200mL/s <0.5 cmH20/L/s semiconductor (0-45°C) FVC, FEV1, FEV1/FVC%, PEF, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, FEF25, FEF50, FEF75, FEF2575, FET, EVol, ELA, FIVC, FIV1, FIV1/FIV FEV1/VC%, TV, VE, RR, t ₁ , t _E , t ₁ /t _{Tot} ,		
Length Thickness Weight			PIF, VC, IVC, IC, ERV,			
Furbine			Memory capacity	VT/t ₁ , MVV Up to 10000 tests		
	Reusable turbine (code 910002 Disposable turbine (code 910004)		Oximetry (on request)	est)		
			Measurement method SpO2 range SpO2 accuracy Average number of heart beats for the	Red and infrared absorption 0-99% ± 2% between 70-99% SpO2 8 beats 30-254 BPM ± 2BPM or 2% 8 seconds		
	Tri-axial accelerometer Rechargeable Lithium-Ion 3.7V, 1100 mAh 1100 mAh		%SpO2 calculation Pulse Rate range Pulse Rate accuracy Average interval for the calculation of			
Consumption Batteries charger	~20-30 mA (during test) voltage=5 V DC, current=minimum 500 mA, Connector : micro USB type B		cardiac pulse Signal quality indication Measured parameters All test	0 - 8 segments on display %SpO _{2MIN} , %SpO _{2MEAN} %SpO _{2MAX} ,		
Autonomy Connectivity Display	compliant with EN 60601-1 50 hours USB 2.0, Bluetooth® 2.1 LCD monochrome, 160×80 pixels			BPM _{MIN} , BPM _{MEAN,} BPM _{MAX} , Ttotal, Tanalysis, T<90%, T<89%, T<88%, T<87%, Ev%SpO ₂ <89, Δ Index, T<40BPM, T>120BPM, Ev<40BPM,		
Keyboard Mouthpieces	Dimension 2.8 inch touchscreen		Sleep test	Ev>120BPM %SpO _{2BASE} , BPM _{BASE} , ODI, Mean Dur.		
Type of electrical protection Safety level for	Ø 30 mm (1.18 inch) Internally powered Type BF Apparatus			Desat., TotDesaturat., Longest Desat., Desatur. Peak, BPM Index, Mean Desaturat., Mean Drop, Max Drop, BPM Variation, NOD4%,		
shock hazard	Type Dr Apparatus			NOD89%, NOD90%, t.NOD4%, t.NOD89%, t.NOD90%		
Conditions of use	Apparatus for continuous use		6MWT test	%SPO2, BPM, Tbaseline, Twalking, Trecovery, Distance, T2%ΔSPO2,		
Storage/shipping conditions	Temperature: Humidity:	MIN -20 °C, MAX + 60 °C MIN 10% RH; MAX 95%RH	Memory capacity	T4%ΔSPO2, Predicted, %Predicted, AUC/Distance, Dyspnea, Dyspnea, Fatigue, Diastolic, Systolic, Steps, VMU, O2-GAP, O2 up to 300 hours oximetry		
Operating conditions	Temperature:	MIN + 10 °C, MAX + 40 °C	Certificates & Registrations			
	Humidity: MIN 10% RH, MAX 95% RH		CE 0476 FDA 510 (k)	MED 9826 K 103530		
Applied norms	IEC 60601-1:2005 + A1:2012 EN 60601-1-2:2015 ISO 80601-2-61:2017 ISO 26782:2009 ISO 23747:2015		Health Canada CND code GMDN code Ministry of Health	71191 (class II), 75535 (class III) Z12150102 (spiro) Z1203020408 (spiro + oxy) 46906 (spiro), 45607 (spiro + oxy) 499389/R (910600), 501050/R		

499389/R (910600), 501 (910606), 501619/R (91 1271090/R (91060011) 1271086/R (9106061) 1271078/R (91061011)



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