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.









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

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



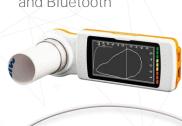
COMPLIANCE ATS/ERS 2019

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





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







DISTINCTIVE features



PREDICTED 6MWT, SLEEP SETS & VALUES TES, HOLTER

Large Selection, including comparison
%Pred, Z-score and LLN.
Include GLI in PC-mode
With Oximetry option, measure desaturation events during exercise, sleep and daily activities



EHR/EMR CONNECTIVITY

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

MAIN FEATURES

Windows-based solution for Spirometry, Oximetry and Telemedicine.

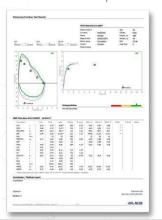
Wide range of predicted sets and values, including GLI Predicted sets, LLN and Z-score. Embedded EHR/EMR

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

connectivity.

MEDICAL REPORT

Specialized and customizable printout



Spiro Connect ■







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: Sp02 (%), Pulse (BPM)

GO-TO-MARKET TOOLKIT

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



Learn more about available SDK and OEM



Compatible TURBINES

| | Mouthpiece | Turbine Disinfection | Turbine Calibration | Packaging | Antiviral Filter |
|-------------------------------|--------------------------|-------------------------|------------------------|---|-------------------------|
| flowMIR TM Disposable Turbine | Included Disposable | Not required | Not required | Individually sealed: 60 or 10 units / box | Available Disposable |
| Reusable 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

| Main body | |
|-----------|------------------------------|
| Width | 48 mm |
| Length | 101 mm |
| Thickness | 16 mm |
| Weight | 99 g (battery pack included) |

Turbine housing Width

47 mm Length 46 mm Thickness 24 mm Weight 17 g

Turbine

Reusable turbine (code 910002

Current capacity Consumption Batteries charger

Autonomy Connectivity Display

Keyboard Mouthpieces Type of electrical protection Safety level for shock hazard

Conditions of use

Storage/shipping conditions

Operating conditions

Applied norms

Disposable turbine (code 910004)

Tri-axial accelerometer Rechargeable Lithium-Ion 3.7V, 1100 mAh 1100 mAh ~20-30 mA (during test) voltage=5 V DC, current=minimum 500 mA, Connector: micro USB type B compliant with EN 60601-1 50 hours USB 2.0, Bluetooth® 2.1 LCD monochrome, 160×80 pixels

Dimension 2.8 inch touchscreen Ø 30 mm (1.18 inch) Internally powered

Type BF Apparatus

Apparatus for continuous use

MIN -20 °C. Temperature: MAX + 60 °C

MIN 10% RH; Humidity: MAX 95%RH

Temperature: MIN + 10 °C, MAX + 40 °C

MIN 10% RH, Humidity: MAX 95%RH

IEC 60601-1:2005 + A1:2012

EN 60601-1-2:2015 ISO 80601-2-61:2017 ISO 26782:2009 ISO 23747:2015

ATS/ERS: 2005, 2019 Update

Spirometry

Flow sensor Flow range Volume accuracy Flow accuracy Dynamic resistance Temperature sensor Measured parameters

bi-directional digital turbine $\pm 16L/s$ ±2.5% or 50mL ±5% or 200mL/s <0.5 cmH2O/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/FIVC%, FEV1/VC%, TV, VE, RR, t_I, t_E, t_I/t_{Tot},

VT/t_I, MVV Up to 10000 tests

Oximetry (on request)

PIF, VC, IVC, IC, ERV,

Memory capacity

Measurement method SpO2 range SpO2 accuracy Average number of heart beats for the %SpO2 calculation Pulse Rate range Pulse Rate accuracy Average interval for the calculation of cardiac pulse

Signal quality indication Measured parameters

All test

Sleep test

6MWT test

Red and infrared absorption

± 2% between 70-99% SpO2 8 beats

30-254 BPM ± 2BPM or 2%

8 seconds

0 - 8 segments on display

 $\begin{array}{l} \mathrm{\%SpO_{2MIN}}, \, \mathrm{\%SpO_{2MEAN}} \, \, \mathrm{\%SpO_{2MAX}}, \\ \mathrm{BPM_{MIN}}, \, \mathrm{BPM_{MEAN}}, \, \mathrm{BPM_{MAX}}, \, \mathrm{Ttotal}, \end{array}$ Tanalysis, T<90%, T<89%, T<88%, T<87%, Ev%SpO₂<89, ΔIndex, T<40BPM, T>120BPM, Ev<40BPM, Ev>120BPM

 $%SpO_{2BASE}$, BPM_{BASE}, ODI, Mean Dur. Desat., TotDesaturat., Longest Desat., Desatur. Peak, BPM Index, Mean Desaturat., Mean Drop, Max Drop, BPM Variation, NOD4%. NOD89%, NOD90%, t.NOD4%, t.NOD89%, t.NOD90%

%SPO2, BPM, Tbaseline, Twalking, Trecovery, Distance, T2%∆SPO2, T4%ΔSPO2, Predicted, %Predicted, AUC/Distance, Dyspnea, Dyspnea, Fatigue, Diastolic, Systolic, Steps,

VMU, 02-GAP, 02 up to 300 hours oximetry

Certificates & Registrations

CE 0476 FDA 510 (k) Health Canada

GMDN code Ministry of Health

CND code

Memory capacity

MED 9826 K 103530

71191 (class II), 75535 (class III) Z12150102 (spiro)

Z1203020408 (spiro + oxy) 46906 (spiro), 45607 (spiro + oxy) 499389/R (910600), 501050/R (910606), 501619/R (910610) 1271090/R (910600I1)

1271086/R (910606I) 1271078/R (910610I1)

