

SPIROLAB®

Desktop, Stand-alone and PC-based Spirometer, with Oximetry Option
All-in-one Spirometer with 7" display, Embedded Printer and Oximetry option, to carry on the go









MAIN features



REAL-TIME

Spirometry: FVC, VC, IVC, MVV, PRE/POST Bronchodilator comparison Oximetry (optional): Spot test (SpO2%, Pulse BPM)



CARRY **EVERYWHERE**

7" LCD Color Touchscreen Display, Long-lasting rechargeable battery, massive Internal Storage



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)



PC CONNECTION **AVAILABLE**

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



CALIBRATION SOFTWARE

Available on device, with printable calibration report (no separate software required)









DISTINCTIVE features



(4)

PREDICTED SETS & VALUES

Large Selection, including GLI, comparison %Pred, Z-score and LLN



PRINTED **EMBEDDED**

Thermal printer. Paper size 112mm. Direct external print also available via PC software

PEDIATRIC INCENTIVE

Real-time animation on display to improve patient compliance during the test

COVID-19 **PREVENTION**

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

Always INCLUDED

- Carrying case
- Power supply/battery charger
- USB cable
- 1 Roll of thermal printer paper

- Noseclip
- PC Software license

With Oximetry Option:

Finger Probe



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.

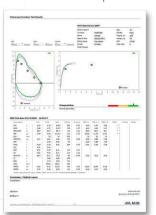
Wide range of predicted sets and values, including GLI Predicted sets, LLN and Z-score. Embedded EHR/EMR

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: SpO2 (%), 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 ™ Disposable Turbine	AMMER Compared to the compare	Included Disposable	Not required	Not required	Individually sealed: 60 or 10 units / box	Available Disposable
Reusable Turbine	A A A III	Required, Not Included	Required	Required	1 unit in Carton box	Required Disposable







TECHNICAL datasheet

PRODUCT CODES - Spirolab Configurations

911080E0 – Spirometer • 911080E1 - Spirometer with reusable turbine

911081E0 - Spirometer + Oximeter • 911081E1 - Spirometer + Oximeter with reusable turbine

Technical specification

Width 220 mm 210 mm Length Thickness 51 mm

Weight 1450 g (battery pack included)

Sensors

miniflowmeter (code 900595) for reusable and disposable turbine dimension (Ø 30 mm, 42 mm)

> Reusable soft, adult, MIR sensor for oximetry tests (code 919024) only

Rechargeable battery and mains

spirolab code 911081

Ni-MH, 6 elements

4500 mAh

Power supply power Current capacity Consumption Backup battery voltage

average 250 mA none Batteries charger Output voltage=12 V, current=1A,

compliant with EN 60601-1

Autonomy ~10 hours USB 2.0, Bluetooth® 2.1 Connectivity Display 7 inch colour touch screen LCD with 800x480 resolution Display Keyboard absent, touchscreen Mouthpieces Ø 30 mm (1.18 inch) Type of electrical Internally powered

Class II while charging battery Protection

Safety level for shock hazard Type BF Apparatus

Conditions of use Apparatus for continuous use

MIN-40°C, Storage conditions Temperature: MAX +70 °C Humidity: MIN 10% RH;

MAX 95%RH

MIN-40°C, Transport conditions Temperature:

MAX +70 °C MIN 10% RH; Humidity:

MAX 95%RH

MIN + 10 °C Operating conditions Temperature: MAX + 40 °C

Humidity: MIN 10% RH, MAX 95%RH

Electrical Safety EN 60601-1 Applied norms Electro Magnetic Compatibility

EN 60601-1-2

Degree of protection IPX1 appliance protected against against water penetration water leaks

Codes and equipments

911080E0 spiro

911080E1 spiro with reusable turbine 911080E2 spiro with 120 FlowMir

911081E0 spiro+oxy

911081E1 spiro+oxy with reusable turbine 911081E2 spiro+oxy with 120 FlowMir

Spirometry

Flow sensor bi-directional digital turbine Volume rate

Flow range $\pm 16L/s$ Volume accuracy Flow accuracy Dynamic resistance Temperature sensor

Test available Measured parameters

0.5,

FEV6, FEF75, EVOL. F1F50, EVC,

RR, ti, Memory capacity 10 L

±2.5% or 50 mL ±5% or 200 mL/s <0.5 cm H20/L/s semiconductor (0-45°C)

FVC, VC, IVC, MVV, PRE-POST FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEF0.5, DTPEF, FEV FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEV2, FEV2/FVC, FEV3, FEV3/FVC, FEV1/FEV6, PEF, FEF25, FEF50, FEF2575, FEF7585, FET, Vext, ELA,

FIVC, FIV1, PIF, FIV1/FIVC, FIF25, FIF75, R50, MVVcal, PIF, IRV, VC IVC, IC, ERV, IRV, FEV1/VC, TV, VE,

te, ti/t-tot, TV/ti, MVV Up to 10000 tests

Oximetry (on request)

Measurement method Red and infrared absorption SpO2 range 0-99%

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 Test available

Measured parameters

± 2% between 70-99% SpO2

8 beats

18-300 BPM

± 2BPM or 2% whichever is greater

8 seconds

0 - 8 segments on display spot

SpO2% min, max, average BPM min, max, average

Test duration

% Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%,

T89%), T5

Memory capacity about 500 hours oximetry

Certificates & Registrations

CE 0476 FDA 510 (k) Health Canada CND code

GMDN code Ministry of Health MED 9826 K 052140 71191 (class II) Z12150102 (spiro)

Z1203020408 (spiro + oxy) 46906 (spiro), 45607 (spiro + oxy)

1272475/R (spiro) 1272476/R (spiro + oxy) 1645455/R (spiro)

