#### ADVANCED

# SPIROBANK II SMART®

Handheld, Stand-alone, Tablet-Based and PC-Based Spirometer, with Oximetry option

A versatile Spirometer and Oximeter, with Tablet (iPad and Android) and PC connection.



## MAIN features



#### **REAL-TIME** TEST

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

#### PC AND TABLET CONNECTION

Real time test on Tablet (via Bluetooth 4.0) and PC (via USB), connect with your EHR/EMR, back-up internal memory and more



#### CARRY 日 **EVERYWHERE**

High resolution backlight 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)



## **DISTINCTIVE** features



#### PREDICTED **SETS & VALUES**

Large Selection, including comparison %Pred, Zscore and LLN. Include GLI on App and PC

#### **INTUITIVE APP** FOR TABLET

Including Virtual via HL7, Calibration check and more

#### **EHR/EMR** CONNECTIVITY

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Via PC, integration with Assistant, data transfer patient database (HL7,GDT) Via Tablet, automatic share to Remote Server



#### COVID-19 PREVENTION

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

#### **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

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- Carrying case
- USB cable
- Noseclip

- V PC Software license With Oximetry Option:
- Finger Probe

## Compatible SOFTWARE

Google Play

Download on the App Store

#### REAL TIME TEST

Spirometry: FVC Pre, FVC Post, VC. Oximetry: SpO2 (%), Pulse (BPM)

Spirometry parameters: FVC, FEV1, FEV1%, PEF, FEF25–75, FET, Lung Age, VC, IVC

Pediatric Incentive (PATENTED)

Calibration (on iOS) with personalized printed report.

#### PC SOFTWARE

Embedded EHR/EMR connectivity (HL7, GDT, more)

NET VERSION available, share one database between different PC workstations

Pediatric Incentive (PATENTED)

Interpretation and Quality Control Grade according to latest Spirometry Standards

Direct integration with your EHR/EMR via HL7 or Exchange

Spirometry: FVC-Pre, FVC-

Oximetry: SpO2 (%), Pulse

Customizable PDF report

PC SOFTWARE

Protocol.

(BPM)

Post, VC-Pre

#### FEATURES

Predicted Sets include GLI, Predicted Values include Zscore and LLN

EHR/EMR direct integration via HL7 standards

Virtual Assistant: during and after the spirometry test.

Customizable PDF Medical Report to print and share

#### REAL TIME TEST

Spirometry: FVC-Pre, FVC-Post, VC-Pre, MVV, Bronchoprovocation tests, Bronchial Challenge

Oximetry: SpO2 (%), Pulse (BPM)

Customizable PDF report

#### MEDICAL REPORT



## Compatible TURBINES

		Mouthpiece	Turbine Disinfection	Turbine Calibration	Packaging	Antiviral Filter
<mark>flowMIR</mark> <sup>™</sup> Disposable Turbine	A CONTRACT OF A	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

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vinspiroPRO

### Spiro Connect

**NIR Spiro App** 



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#### PLAY VIDEO

## Also available in MORE CONFIGURATIONS





Technical Specification	Spirobank II Smart	Spirobank II Basic
TYPE OF SPIROMETER	StandAlone + PC + App, with Oximetry Option	StandAlone + PC
COMPATIBLE TURBINES	flowMIR™ Disposable Turbine, Reusable Turbine Flowmeter	flowMIR™ Disposable Turbine, Reusable Turbine Flowmeter
COMPATIBLE SOFTWARES	MIR Spiro App, Winspiro PRO, spiro Connect	Winspiro PRO, spiro Connect
EXTERNAL CONTROL	Real-Time test on Tablet screen and PC screen, connect with your EHR/EMR, back-up internal memory, and much more Connect to your PC via USB (no Bluetooth) Connect to your Tablet via Bluetooth Smart BLE 4.0	Real-Time test on PC screen, connect with your EHR/EMR, back-up internal memory and much more Connect to your PC via USB
EHR CONNECTIVITY	Via PC: integration with patient database on your EHR/EMR (in HL7, GDT) Via APP: transfer data to a remote server in HL7 standards	Via PC, integration with patient database on your EHR/EMR (in HL7, GDT)
MEASURED PARAMETERS	Spirometry: FVC, VC, IVC, MVV, PRE- POST Bronchodilator comparison Oximetry (optional): Spot test (SpO2, BPM) Spirometry: FVC, FEV1, FEV1/FVC%, DTPEF, FEV 0.5, FEV0.5/FVC%, FEV2, FEV0.75, FEV0.75/FVC%, FEV2, FEV2/FVC%, FEV3, FET3, FET5, FEF50, FE75, FEF25-75, FEF75-85%, FET, Vext, ELA, EV0L, FIVC, FIV1, PIF, FIV1/FIVC%, FIF25, FIF50, FIF75, R50, PIF, IRV, VC, IVC, IC, ERV, FEV1/VC%, TV, VE, RR, t1, tE, t1/t-tot, TV/t1, MVV Oximetry (Optional): SpO2% (min, max, average), BPM (min, max, average), Test duration, % Bradycardia Duration (<40 BPM), % of Time with SpO2 $\leq$ 90% (T90%, T89%) on MIR Spiro App: Spirometry: FVC, VC, PRE/POST Bronchodilator comparison Parameters: FVC, FEV1, FEV1%, PEF, FEF25–75, FET, Lung Age, VC, IVC. Oximetry (Optional): %SpO2 [Baseline, Min, Max, Mean], Pulse Rate [Baseline, Min, Max, Mean] Events.	Spirometry: FVC, VC, IVC, PRE/POST Bronchodilator comparison Spirometry: FVC, VC, IVC, IC, ERV, FEV1, FEV1%, PEF, FEF 25-75, FET, EVOL, ELA



## **TECHNICAL** datasheet

PRODUCT CODES - Spirobank II Smart Configurations 911028E0 – Spirometer • 911028E1 - Spirometer with reusable turbine 911029E0 - Spirometer + Oximeter • 911029E1 - Spirometer + Oximeter with reusable turbine

Technical specification			Spirometry		
Width Length Thickness Weight	55 mm 160 mm 25 mm 140 g (battery pack included)		Flow sensor Flow range Volume accuracy Flow accuracy Dynamic resistance	bi-directional digital turbine ±16L/s ±2.5% or 50 mL ±5% or 200 mL/s <0.5 cm H2O/L/s semiconductor (0-45°C) FVC, VC, IVC, MVV, PRE-POST FVC, FEV1, FEV1/FVC%, DTPEF, FEV 0.5, FEV0.5/FVC%, FEV0.75, FEV0.75/FVC%, FEV2, FEV2/FVC%, FEV3_FEV3/EVC% FEV6	
Turbine	Turbine Reusable turbine (code 910002		Temperature sensor		
			Measured parameters		
	Disposable turbine	(code 910004)		FEV3, FEV3/FVC %, FEV6, FEV1/FEV6%, PEF, FEF25, FEF50, FEF75, FEF25-75, FEF75-85%, FET,	
Power supply	Rechargeable Lith 1100 mAh	nium-Ion 3.7V,		Vext, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC%, FIF25, FIF50, FIF75, R50, PIF, IRV, VC, IVC, IC, ERV,	
Current capacity	1100 mAh			FEV1/VC%, TV, VE, RR, t <sub>1</sub> , t <sub>F</sub> , t <sub>1</sub> /t- <sub>tot</sub> ,	
Consumption ~20-30 mA (duri Batteries charger voltage=5 V DC, current=minimum Connector: micro		ng test) n 500 mA, USB B-type	Memory capacity	TV/t <sub>I</sub> , MVV Up to 10000 tests	
	compliant with EN	V 60601-1	Oximetry (on request)		
Autonomy	50 hours			4	
Connectivity Display Keyboard Mouthpieces Type of electrical protection Safety level for	USB 2.0, Bluetooth <sup>®</sup> 4.0 LCD monochrome, 160 × 80 pixel membrane keyboard with 6 keys Ø 30 mm (1.18 inch) Internal power supply		Measurement method SpO2 range SpO2 accuracy Average number of heart beats for the %SpO2 calculation Pulse Rate	Red and infrared absorption 0-99% ± 2% between 70-99% SpO2 8 beats	
shock hazard	турс вт пррагате	13	Range	30-300 BPM	
Conditions of use	Apparatus for cor	ntinuous use	Accuracy	± 2BPM or 2% whichever is greater	
Conditions of storage	Temperature: Humidity:	MIN -20 °C, MAX + 60 °C MIN 10% RH; MAX 05% PH	Averaging interval for Signal quality indication Test available Measured parameters	8 seconds average 0 - 8 segments on display spot SpO2% min, max, average	
		IVIAA 9570KH		Test duration	
Operating Conditions	Temperature:	MIN + 10 °C, MAX + 40 °C		% Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM)	
	Humidity:	MIN 10% RH, MAX 95%RH	Mamany appagity	% of Time with SpO2 $\leq$ 90% (T90%, T89%)	
Applied norms	Electrical Safety Standard IEC 60601-1:2005 + A1: 2012 Electro Magnetic Compatibility EN 60601-1-2:2015 ISO 26782: 2009 ISO 23747: 2015 ATS/ERS: 2005, 2019 update		Memory capacity	up to 300 hours oximetry	
			Certificates & Registrations		
			CE 0476 FDA 510 (k) CND code	MED 9826 K 061712 Z12150102 (spiro) Z1203020408 (spiro + oxi)	
			GMDN code	46906 (spiro), 45607 (spiro + oxi)	



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