

Personal Smart

# SPIROBANK<sup>TM</sup>

## OXI

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App-Based Spirometer with  
embedded Oximeter.

The simplest device for accurate  
Remote Patient Monitoring and  
Homecare. Real time test available on  
Smartphone via Bluetooth Smart 4.0



# MAIN features



## AUTOMATIC PAIR AND PLAY

Automatic pairing via Bluetooth BLE. Real-time test result on your Smartphone



## MEASURED PARAMETERS

Spirometry Parameters: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FET, FEF25, FEF50, FIVC, FIV1, PIF, FEV3, FEV05, FEV075, FEV2

Oximetry Parameters: %SpO2min, %SpO2mean, %SpO2max, BPMmin, BPMmean, BPMmax, Ttotal



## 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 Pending



# DISTINCTIVE features



## SPIROMETRY GUIDELINES

Suitable for all ages from 5 to 93 years and multi-ethnic groups (GLI predicted sets)



## REAL-TIME OXIMETRY

Innovative reflectance pulse-oximetry sensor (Touch). Easy to use and accurate.



## MEDICAL REPORT

Share with anyone at anytime via eMail, Whatsapp, SMS, Cloud, Drive and other Apps



## COVID-19 PANDEMIC

Avoid going to the hospital or medical offices during COVID-19 pandemic

## 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



# Always INCLUDED

- 2x AAA 1.5V Batteries
- Single Patient Reusable Turbine
- Plastic reusable mouthpiece
- User manual
- App for Smartphone (iOS and Android)

# Compatible SOFTWARE

## MIR SPIROBANK APP

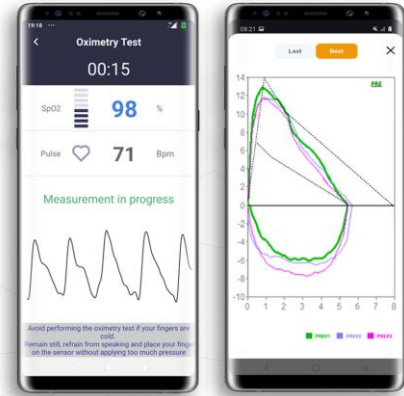
Mobile App (iOS and Android), for real time spirometry and oximetry test, directly on your Smartphone via Bluetooth Smart 4.0



### REAL TIME TEST

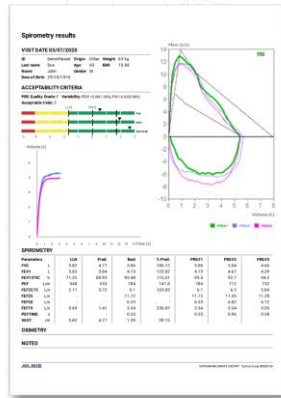
Spirometry: PEF, FVC, FEV1, FEV1/FVC ratio, FEF25/75, FEV6, VEXT, DTPEF, FEF75, FEF25, FEF50.

Oximetry: SpO2% (mean), Pulse BPM (mean)



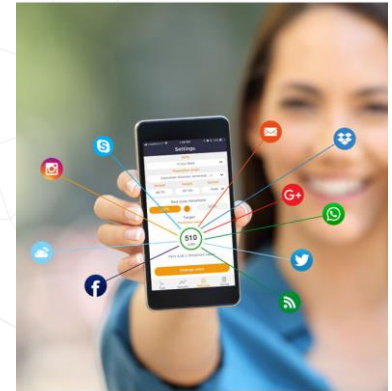
### MEDICAL REPORT

Professional PDF report Including Acceptability Messages, Quality Control Grade, Acceptable Trials, Variability of FEV1 and FVC, Pictograms



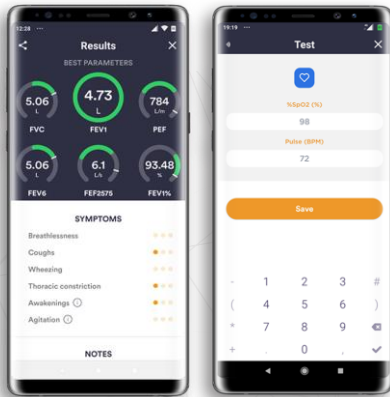
### SHARE RESULTS

Share results in PDF With anyone at anytime via eMail, Whatsapp, SMS, Cloud, Drive Bluetooth, Airdrop and other Apps



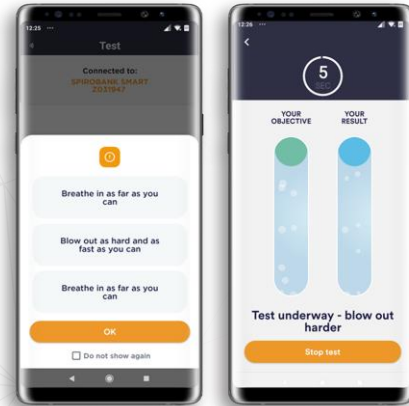
### PERSONAL TREND

E-diary, symptoms and notes can be added for each test. Oximetry results can also be added manually on the App



### INCENTIVE

Real time animation on Smartphone, to improve personal compliance during the test



# Compatible TURBINES

Single Patient Reusable Turbine



flowMIR™ Disposable Turbine



	Mouthpiece	Turbine Disinfection	Turbine Calibration	Packaging	Antiviral Filter
Single Patient Reusable Turbine	Included Reusable	Not required	Not required	Individually sealed: 1 unit / box	Not required
flowMIR™ Disposable Turbine	Included Disposable	Not required	Not required	Individually sealed: 60 or 10 units / box	Not required



PLAY VIDEO REVIEW



SCIENTIFIC PUBLICATIONS



# TECHNICAL datasheet

PRODUCT CODE 911125

## Technical specification

Width	49 mm
Length	109 mm
Thickness	21 mm
Weight	60.7 g (batteries included)

### Turbine



Reusable Turbine with plastic Mouthpiece (code 910013)



Disposable Turbine (code 910004)

Mouthpiece	Ø 30 mm (1.18 inches)
Power supply	2 batteries AAA 1.5 V
Consumption	max 12 mA average 8 µA (Stand by)

Autonomy	5-10 years
IP protection level	IP22
Connectivity	Bluetooth® 4.0
Type of electrical protection	Internally powered
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use

Storage conditions	Temperature:	MIN -25 °C, MAX + 70 °C
	Humidity:	MIN 10% RH; MAX 93% RH

Operating Conditions	Temperature:	MIN + 5 °C, MAX + 40 °C
	Humidity:	MIN 15% RH, MAX 93% RH

Shipping conditions	Temperature:	MIN -25 °C MAX + 70 °C
	Humidity:	MIN 10% RH; MAX 93% RH

Applicable standards	ATS/ERS: 2005, 2019 Update
	ISO 26782: 2009
	ISO 23747: 2015
	ISO 14971: 2019
	ISO 10993-1: 2018
	2011/65/UE Directive
	EN ISO 15223: 2016
	IEC 60601-1: 2005+Amd1:2012
	EN 60601-1-2: 2015
	IEC 60601-1-6: 2010+Amd2013
	EN 60601-1-11: 2015
	ISO 80601-2-61: 2017

## Spirometry

Flow sensor	bi-directional digital turbine
Flow range	16L/s (960 L/m)
Volume range	10 L
Volume accuracy	±2.5% o ±0.05L
Flow accuracy	±5.0% o 0,20 L/s
Dynamic resistance	<0.5 cm H <sub>2</sub> O/L/s (a 12 L/s)
Temperature sensor	none
Available test	FVC
Measured parameters	FEV1, PEF, FVC, FEV1/FVC, FEV6, FEF2575
Additional parameters available with F/V version	FIVC, FIV1, PIF FEF25, FEF50, FEF75, EVol, FEV05, FEV075, FEV2, FEV3, FET, PEF Time
Memory capacity	the application on the remote device (smartphone/tablet) memorizes data

## Oximetry

Measuring method	double wavelength
%SpO <sub>2</sub> range	70%-100%
%SpO <sub>2</sub> accuracy	±1.9%
Average number of beats for the %SpO <sub>2</sub> calculation	12 beats
Pulse Rate range	30-200 BPM
Pulse Rate accuracy	±3%
Average interval for Pulse rate calculation	12 seconds
Quality signal indicator	0-8 lines
Available tests	spot
Measured parameters	%SpO <sub>2</sub> MIN, %SpO <sub>2</sub> MEAN, %SpO <sub>2</sub> MAX, BPM <sub>MIN</sub> , BPM <sub>MEAN</sub> , BPM <sub>MAX</sub> , T <sub>TOTAL</sub>
Wavelength sensors	Red 660 nm Infrared 880 nm
Maximum optical output power	1.2 mW

## Certification & Registration

CE 0476	MED 9826
FDA 510 (k)	pending
Health Canada	pending
Codice CND	Z12150102
Codice GMDN	46906

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