SPIROBANK™

OXI

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

SPIROBANK OXI

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.

LIVE VIDEO EXAM

Connect with your Healthcare provider in real-time, from the comfort of your home

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

Up- to 30 Spirometry parameters and 8 Oximetry parameters available via SDK!

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

GET IT ON
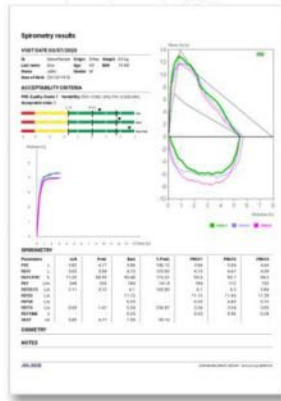Google Play

Download on the
App Store

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 Acceptabilty 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
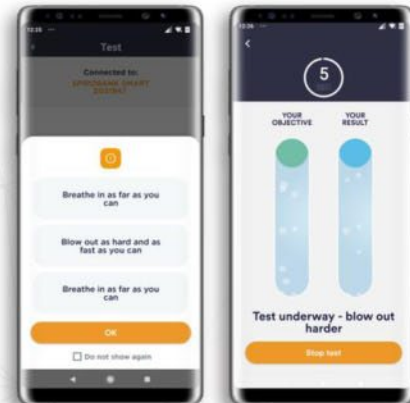
PERSONAL TREND

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

	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

Also available in MORE CONFIGURATIONS

Technical Specification	Spirobank Oxi	Spirobank Smart	Smart One OXI	Smart One
TYPE OF SPIROMETER	App-Based, for Remote Patient Monitoring, with Oximetry Option	App-Based, for Remote Patient Monitoring	App-Based, for Personal Care, with Oximetry Option	App-Based, for Personal Care
COMPATIBLE TURBINES	flowMIR™ Disposable Turbine, Single Patient Reusable Turbine	flowMIR™ Disposable Turbine, Single Patient Reusable Turbine	Single Patient Reusable Turbine	Single Patient Reusable Turbine
COMPATIBLE SOFTWARES	MIR Spirobank App	MIR Spirobank App, iSpirometry App	Smart One App	Smart One App
EXTERNAL CONTROL	Real time plethysmographic curve and test result on SmartPhone screen. No internal memory, no display. Data are not stored in the device memory. Connect to your Smartphone via Bluetooth Smart BLE 4.0	Real time test on Smartphone screen. No internal memory, no display. Data are not stored in the device memory. Connect to your Smartphone via Bluetooth Smart BLE 4.0	Real time plethysmographic curve and test result on SmartPhone/Tablet screen. No internal memory, no display. Data are not stored in the device memory. Connect to your Smartphone/Tablet via Bluetooth Smart BLE 4.0	Real time test on SmartPhone/Tablet screen. No internal memory, no display. Data are not stored in the device memory. Connect to your Smartphone/Tablet via Bluetooth Smart BLE 4.0
EHR CONNECTIVITY	Ready-to-Connect with 3rd party Apps for Professional and Personal Care and Clinical Trials	Ready-to-Connect with 3rd party Apps for Professional and Personal Care and Clinical Trials	Ready-to-Connect with 3rd party Apps for Professional and Personal Care and Clinical Trials	Ready-to-Connect with 3rd party Apps for Professional and Personal Care and Clinical Trials
REAL TIME TEST	Simple and intuitive App for Smartphone, always included for iOS and Android. E-diary, symptoms and notes can be added for each test. Test Results can be shared in PDF (via Whatsapp, E-mail, other Apps), and printed directly (via Bluetooth printer). Real time animation, to help performing a good test. Easy to read Spirometry Guidelines for test compliance. Real time plethysmographic curve.	Simple and intuitive App for Smartphone, always included for iOS and Android. E-diary, symptoms and notes can be added for each test. Test Results can be shared in PDF (via Whatsapp, E-mail, other Apps), and printed directly (via Bluetooth printer). Real time animation, to help performing a good test. Easy to read Spirometry Guidelines for test compliance.	Simple and intuitive App for Smartphone and Tablet, always included for iOS and Android. E-diary, symptoms and notes can be added for each test. Test Results can be shared in PDF (via Whatsapp, E-mail, other Apps), and printed directly (via Bluetooth printer). Real time animation, to help performing a good test. Easy-to-read graphic trends for self-assessment. Real time plethysmographic curve.	Simple and intuitive App for Smartphone and Tablet, always included for iOS and Android. E-diary, symptoms and notes can be added for each test. Test Results can be shared in PDF (via Whatsapp, E-mail, other Apps), and printed directly (via Bluetooth printer). Real time animation, to help performing a good test. Easy-to-read graphic trends for self-assessment.
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. on MIR Spirobank App: Spirometry Parameters: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FEF25, FEF50. Oximetry Parameters: SpO2 (%), Pulse (BPM)	Spirometry Parameters: PEF, FVC, FEV1, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FET, FEF25, FEF50, FIVC, FIV1, PIF, FEV3, FEV05, FEV075, FEV2. on MIR Spirobank App: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FEF25, FEF50. on iSpirometry App: PEF, FVC, FEV1, FEV1/FVC, FEF2575, FEV6	Spirometry Parameters: PEF, FEV1. Oximetry Parameters: %SpO2min, %SpO2mean, %SpO2max, BPMmin, BPMmean, BPMmax, Ttotal. on MIR Smart One App: Spirometry Parameters: PEF, FEV1. Oximetry Parameters: SpO2 (%), Pulse (BPM)	Spirometry Parameters: PEF, FEV1

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 H2O/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
%SpO2 range	70%-100%
%SpO2 accuracy	±1.9%
Average number of beats for the %SpO2 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	$\%SpO_{2MIN}$, $\%SpO_{2MEAN}$, $\%SpO_{2MAX}$, BPM_{MIN}, BPM_{MEAN}, BPM_{MAX} T_{TOTAL}
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

Subject to Change