Personal Smart

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 5-ready









MAIN features



AUTOMATIC PAIR AND PLAY

Automatic pairing via Bluetooth. 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



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



Oximetry Parameters: %Sp02min, %Sp02mean, %Sp02max, BPMmin, BPMmean, BPMmax, Ttotal



DISTINCTIVE features



SPIROMETRY GUIDELINES

Suitable for all ages from 5 to 93 years and multiethnic 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 5-ready

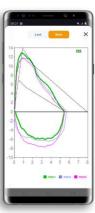


REAL TIME TEST

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

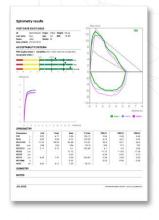
Oximetry: SpO2% (mean), Pulse BPM (mean)





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





required

Compatible **TURBINES**

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



Turbine



Disposable



required

10 units / box

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 5-ready	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 5-ready	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 5-ready	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 5-ready
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, ETVC, FTV1 PIE	Spirometry Parameters: PEF, FVC, FEV1, FEV1/FVC, FEF2575, FEV6, VEXT, DTPEF, FEF75, FET, FEF25, EEEE6, ETVC, ETV4, PTE, FEFV3	Spirometry Parameters: PEF, FEV1 Oximetry Parameters: %Sp02min, %Sp02mean	Spirometry Parameters: PEF, FEV1

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

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

%SpO2min, %SpO2mean, %SpO2max, BPMmin, BPMmean, BPMmax, Ttotal





on MIR Smart One App: Spirometry Parameters:

PEF, FEV1
Oximetry Parameters: SpO2
(%), Pulse (BPM)

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)

Ø 30 mm (1.18 inches)

average 8 µA (Stand by)

2 batteries AAA 1.5 V

Bluetooth® 5-ready

Internally powered

Type BF Apparatus

Temperature:

Temperature:

Temperature:

Humidity:

Humidity:

Apparatus for continuous use

MIN -25 °C,

MAX + 70 °C

MIN 10% RH;

MAX 93% RH

MIN + 5 °C,

MAX + 40 °C

MIN 15% RH.

MAX 93% RH

MIN -25 °C MAX + 70 °C

MIN 10% RH;

MAX 93% RH

max 12 mA

5-10 years

IP22

Disposable Turbine (code 910004)

Mouthpiece **Power supply** Consumption

Autonomy IP protection level Connectivity Type of electrical protection Safety level for shock hazard

Conditions of use Storage conditions

Operating Conditions

Shipping conditions

Applicable standards

ATS/ERS: 2005, 2019 Update

Humidity:

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

FEV1, PEF, FVC, FEV1/FVC, **Measured parameters**

FEV6, FEF2575

Additional parameters available with F/V version **Memory capacity**

FIVC, FIV1, PIF FEF25, FEF50, FEF75, EVol. FEV05, FEV075, FEV2, FEV3, FET, PEF Time

the application on the remote device (smartphone/tablet) memorizes data

Oximetry

Measuring method double wavelength %SpO2 range 70%-100% ±1.9% %SpO2 accuracy Average number of beats 12 beats

for the %SpO2 calculation

30-200 BPM **Pulse Rate range Pulse Rate accuracy** ±3% Average interval for 12 seconds

Pulse rate calculation Quality signal indicator **Available tests**

spot **Measured parameters**

%SpO_{2MIN}, %SpO_{2MEAN},

 $%SpO_{2MAX}$,

0-8 lines

BPM_{MIN}, BPM_{MEAN}, BPM_{MAX}

 T_{TOTAL} Red 660 nm **Wavelength sensors**

Infrared 880 nm **Maximum optical** 1.2 mW

output power

Certification & Registration

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

