Personal Smart

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SPIROBANK®

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





SPIROBANK OXI







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

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 Cleared.



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

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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**

Mobile App (iOS and Android), for real time **spirometry and oximetry** test, directly on your Smartphone via Bluetooth 5-ready

MEDICAL REPORT

Professional PDF report

Including Acceptabilty

Variability of FEV1 and FVC, Pictograms

Messages, Quality

Acceptable Trials,

Control Grade,



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REAL TIME TEST

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

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





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



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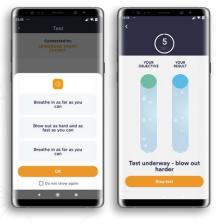
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INCENTIVE

SCIENTIFIC PUBLICATIONS

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



Compatible **TURBINES**

PLAY VIDEO REVIEW

Cingle Dationt	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
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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 Car
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 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 note can be added for each test. Test Results can be shared 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: %Sp02min, %Sp02mean, %Sp02max, BPMmin, BPMmean, BPMmax, Ttotal on MIR Spirobank App: Spirometry Parameters: PEF, FEV1, FVC, FEV1/FVC, FEF2575, FEV3, VEXT, DTPEF, FEF75, FEF25, FEF50 Oximetry Parameters: Sp02 (%), 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: %Sp02min, %Sp02mean, %Sp02max, BPMmin, BPMmean, BPMmax, Ttotal on MIR Smart One App: Spirometry Parameters: PEF, FEV1 Oximetry Parameters: Sp02 (%), Pulse (BPM)	Spirometry Parameters: PE FEV1



TECHNICAL datasheet PRODUCT CODE 911125

Technical specification

Width Length Thickness Weight

Turbine

49 mm 109 mm 21 mm 60.7 g (batteries included)

Reusable Turbine with plastic Mouthpiece (code 910013)



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

Disposable Turbine (code 910004)

Ø 30 mm (1.18 inches) 2 batteries AAA 1.5 V max 12 mA average 8 µA (Stand by) 5-10 years IP22 Bluetooth® 5-ready Internally powered

Type BF Apparatus

Apparatus for continuous use

MIN -25 °C, Temperature: MAX + 70 °C Humidity: MIN 10% RH; MAX 93% RH Temperature: MIN + 5 °C, MAX + 40 °C Humidity: MIN 15% RH. MAX 93% RH

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

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 Flow range Volume range Volume accuracy Flow accuracy Dynamic resistance **Temperature sensor Available test Measured parameters Additional parameters** available with F/V version Memory capacity

bi-directional digital turbine 16L/s (960 L/m) 10 L ±2.5% o ±0.05L ±5.0% o 0.20 L/s <0.5 cm H2O/L/s (a 12 L/s) none FVC FEV1, PEF, FVC, FEV1/FVC, FEV6, FEF2575 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 %SpO2 range %SpO2 accuracy Average number of beats for the %SpO2 calculation **Pulse Rate range Pulse Rate accuracy** Average interval for **Pulse rate calculation Quality signal indicator Available tests Measured parameters**

Wavelength sensors

Maximum optical output power

Certification & Registration

CE 0476 FDA 510 (k) **Health Canada Codice CND Codice GMDN**

70%-100% $\pm 1.9\%$ 12 beats 30-200 BPM ±3% 12 seconds 0-8 lines spot

double wavelength

%SpO_{2MIN}, %SpO_{2MEAN}, %SpO_{2MAX}, BPM_{MIN}, BPM_{MEAN}, BPM_{MAX} T_{TOTAL} Red 660 nm Infrared 880 nm 1.2 mW

MED 9826 cleared pending Z12150102 46906



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