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 Smart 4.0









MAIN features



PAIR AND PLAY

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



MOBILE APP

Intuitive App for Spirometry and Oximetry, always included for iOS and Android Smartphones.





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.

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





DISTINCTIVE features



SPIROMETRY GUIDELINES

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



REAL TIME OXIMETRY TEST

Innovative reflectance pulseoximetry sensor (Touch). Easy to use and accurate.



SHARE MEDICAL REPORT ON APP

With anyone at anytime via eMail, Whatsapp, SMS, Cloud, Drive Bluetooth, Airdrop and more.

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

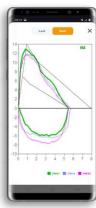


REAL TIME TEST

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

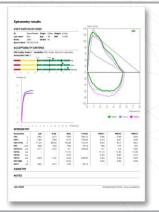
Oximetry: SpO2% (mean), Pulse BPM (mean)





MEDICAL REPORT

Professional PDF report Including 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 more.



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**

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







TECHNICAL datasheet



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

Technical specification

Width 49 mm 109 mm Length 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) 2 batteries AAA 1.5 V Power supply

Consumption max 12 mA

average 8 µA (Stand by)

5-10 years Autonomy IP22 IP protection level

Bluetooth® 4.0 Connectivity Type of electrical Internally powered protection

Safety level for shock hazard

Conditions of use Apparatus for continuous use

Storage conditions Temperature: MIN -25 °C, MAX + 70 °C

Type BF Apparatus

Humidity: MIN 10% RH;

MAX 93% RH MIN + 5 °C, Temperature:

Operating Conditions MAX + 40 °C

Humidity: MIN 15% RH, MAX 93% RH

Shipping conditions Temperature: MIN -25 °C

MAX + 70 °CHumidity: MIN 10% RH: Spirometry

bi-directional digital turbine Flow sensor

Flow range 16L/s (960 L/m)

Volume range 10 L

 $\pm 2.5\%$ o ± 0.05 L Volume accuracy ±5.0% o 0,20 L/s Flow accuracy

<0.5 cm H2O/L/s (a 12 L/s) Dynamic resistance none

Temperature sensor Available test FVC

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

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

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

Pulse rate calculation

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} Red 660 nm

Wavelength sensors

Infrared 880 nm 1.2 mW

Maximum optical

output power

Certification & Registration

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



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