

Personal Smart

# SPIROBANK<sup>TM</sup> SMART

App-Based Spirometer

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



# MAIN features



## AUTOMATIC PAIR AND PLAY

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



## MEASURED PARAMETERS

**Spirometry Parameters on App:** FVC, FEV1, FEV1/FVC, PEF, FEF2575, FEF25, FEF50, FEF75, DTPEF, VEXT, FEV6



## COMPLIANCE ATS/ERS 2019

And other Standards including ISO 26782 (for Spirometry), ISO 23747 (for PEF), and more. CE0476, FDA 510 (k)



## MOBILE APP INCLUDED

Intuitive App for self-management of lung conditions, always included for iOS and Android



# DISTINCTIVE features



## SPIROMETRY GUIDELINES

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



## COVID-19 PANDEMIC

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



## LIVE VIDEO EXAM

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



## READY TO CONNECT

With 3rd party Apps for Professional Care, Personal Care and Clinical Trials

## 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 19 Spirometry 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

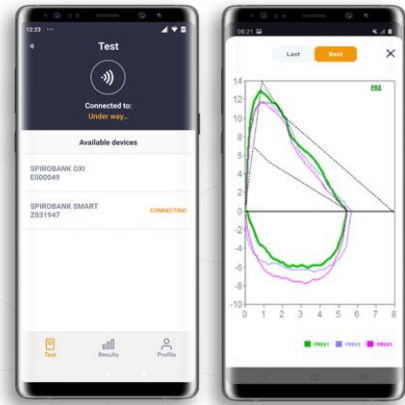
Mobile App (iOS and Android), for real time **Spirometry** test, directly on your Smartphone via **Bluetooth**

Add **Oximetry** results manually on the APP



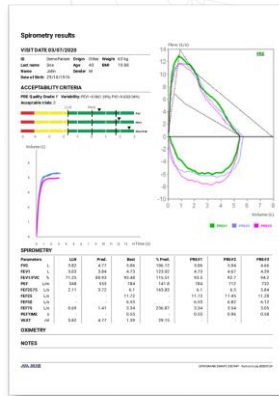
### REAL TIME TEST

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



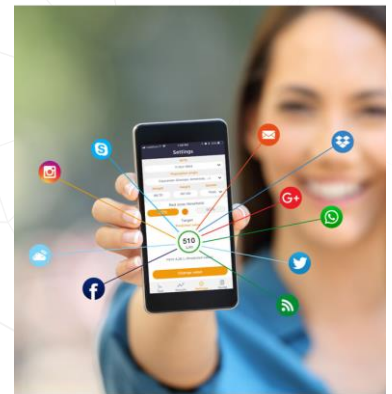
### MEDICAL REPORT

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



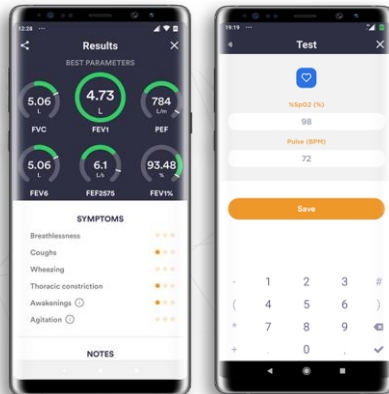
### SHARE RESULTS

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



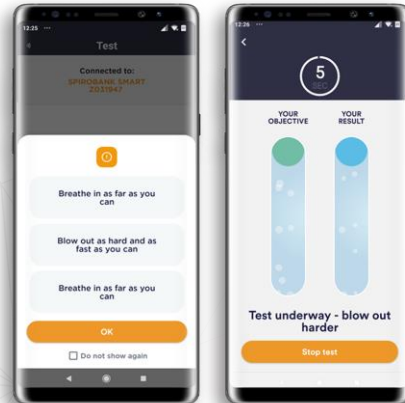
### PERSONAL TREND

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



Mouthpiece

Included Reusable

Turbine Disinfection

Not required

Turbine Calibration

Not required

Packaging

Individually sealed: 1 unit / box

Antiviral Filter

Not required

flowMIR™ Disposable Turbine



Included Disposable

Not required

Not required

Individually sealed: 60 or 10 units / box

Not required



PLAY VIDEO



SCIENTIFIC PUBLICATIONS



# TECHNICAL datasheet

PRODUCT CODE 911105P51

## Technical specification

<b>Width</b>	49 mm
<b>Length</b>	109 mm
<b>Thickness</b>	21 mm
<b>Weight</b>	60.7 g (batteries included)

### Turbine



Reusable Turbine with plastic Mouthpiece (code 910013)



Disposable Turbine (code 910004)

<b>Power supply</b>	2 batteries AAA 1.5 V
<b>Consumption</b>	max 12 mA Stand by 8 $\mu$ A medium
<b>Backup battery voltage</b>	none
<b>Batteries charger</b>	none
<b>Autonomy</b>	5-10 years (Stand by)
<b>Connectivity</b>	Bluetooth® 4.0 for S/N < Z099220

Bluetooth® 5 ready  
for S/N > Z099220

<b>Mouthpieces</b>	Ø 30 mm (1.18 inch)
<b>Type of electrical protection</b>	Internally powered
<b>Safety level for shock hazard</b>	Type BF Apparatus
<b>IP protection level</b>	IP22
<b>Conditions of use</b>	Apparatus for continuous use

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

<b>Operating Conditions</b>	Temperature:	MIN +5 °C, MAX +40 °C
	Humidity:	MIN 10% RH, MAX 93%RH

<b>Shipping conditions</b>	Temperature:	MIN -25 °C, MAX + 70 °C
	Humidity:	MIN 10% RH; MAX 93%RH

### Applicable standards

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

### Spirometry

<b>Flow sensor</b>	bi-directional digital turbine
<b>Flow range</b>	±16L/s
<b>Volume accuracy</b>	±2.5% or 0,05 L
<b>Flow accuracy</b>	±5.0% or 0,20 L/s
<b>Dynamic resistance</b>	<0.5 cm H <sub>2</sub> O/L/s
<b>Temperature sensor</b>	none
<b>Test available</b>	FVC,
<b>Measured parameters</b>	FEV1, PEF, FVC, FEV1/FVC ratio, FEV6, FEF2575

<b>Additional parameters available with F/V version</b>	FIVC, FIV1, PIF FEF25, FEF50, FEF75, EVol, FEV05, FEV075, FEV2, FEV3, FET, PEF Time
---	---

<b>Memory capacity</b>	the application on the smart phone memorizes data
------------------------	---

### Certificates & Registrations

<b>CE 0476</b>	MED 9826 by Kiwa-Cermet
<b>FDA 510(k)</b>	K072979
<b>CND code</b>	Z12150102
<b>GMDN code</b>	46906