

# SPIROBANK<sup>TM</sup> SMART

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App-Based Spirometer

The simplest device for accurate  
Remote Patient Monitoring and  
Homecare. Real time test available on  
Smartphone via Bluetooth Smart 4.0



## MAIN features



### AUTOMATIC PAIR AND PLAY

Automatic pairing via Bluetooth BLE. Real-time test result 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 30 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

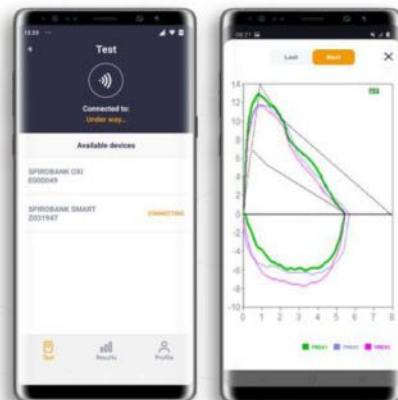
Mobile App (iOS and Android), for real time Spirometry test, directly on your Smartphone via Bluetooth Smart 4.0

Add Oximetry results manually on the APP



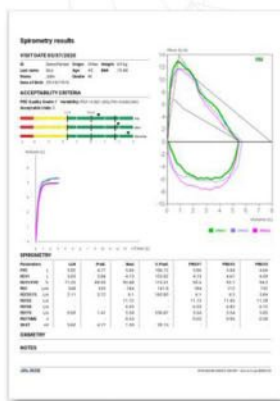
#### REAL TIME TEST

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

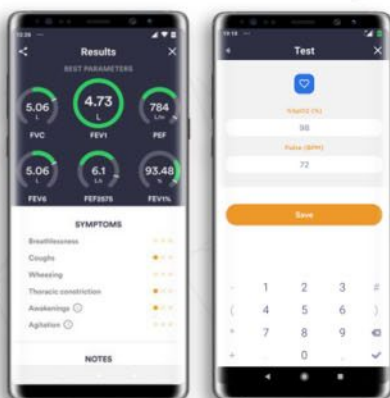
Share results in PDF With anyone at anytime via eMail, Whatsapp, SMS, Cloud, Drive Bluetooth, Airdrop and other Apps



### PERSONAL TREND

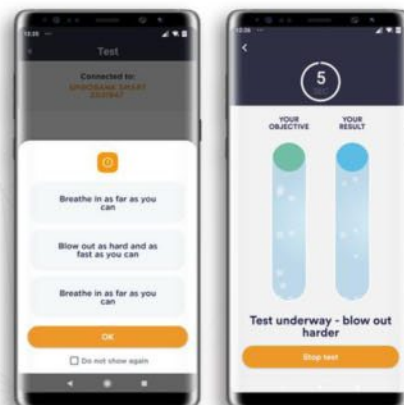
E-diary, symptoms and notes can be added for each test.

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<sup>TM</sup> 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 Smart	Spirobank Oxi	Smart One	Smart One OXI
<b>TYPE OF SPIROMETER</b>	App-Based, for Remote Patient Monitoring	App-Based, for Remote Patient Monitoring, with Oximetry Option	App-Based, for Personal Care	App-Based, for Personal Care, with Oximetry Option
<b>COMPATIBLE TURBINES</b>	flowMIR™ Disposable Turbine, Single Patient Reusable Turbine	flowMIR™ Disposable Turbine, Single Patient Reusable Turbine	Single Patient Reusable Turbine	Single Patient Reusable Turbine
<b>COMPATIBLE SOFTWARES</b>	MIR Spirobank App, iSpirometry App	MIR Spirobank App	Smart One App	Smart One App
<b>EXTERNAL CONTROL</b>	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 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/ 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 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
<b>EHR CONNECTIVITY</b>	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
<b>REAL TIME TEST</b>	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, 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 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.	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.
<b>MEASURED PARAMETERS</b>	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, 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, FEV1	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)

# TECHNICAL datasheet

PRODUCT CODE 911105

## 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)

Power supply	2 batteries AAA 1.5 V
Consumption	max 12 mA Stand by 8 $\mu$ A medium
Backup battery voltage	none
Batteries charger	none
Autonomy	5-10 years (Stand by)
Connectivity	Bluetooth@4.0
Mouthpieces	$\varnothing$ 30 mm (1.18 inch)
Type of electrical protection	Internally powered
Safety level for shock hazard	Type BF Apparatus
IP protection level	IP22
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 10% RH, MAX 93%RH
Shipping conditions	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

Flow sensor	bi-directional digital turbine
Flow range	$\pm$ 16L/s
Volume accuracy	$\pm$ 2.5% or 0,05 L
Flow accuracy	$\pm$ 5.0% or 0,20 L/s
Dynamic resistance	<0.5 cm H <sub>2</sub> O/L/s
Temperature sensor	none
Test available	FVC,
Measured parameters	FEV1, PEF, FVC, FEV1/FVC ratio, 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 smart phone memorizes data

## Certificates & Registrations

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