MIR

Spirobank Smart and Spirobank Oxi

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Spirometer designed for screening, home care, and clinical trials

Spirobank Smart

Spirobank Smart is a **portable app-based spirometer** that allows for **easy** and **quick** monitoring of lung functions, with the same accuracy as hospital-grade devices.

Spirobank Oxi

Spirobank Oxi adds **oximetry** to **spirometry**, allowing the measurement of blood oxygen levels (**Sp02%**) and heart rate (**BPM**) through an **integrated touch oximeter**.

Main features

- Integration with **Remote Patient Monitoring** systems (DDS, SDK)

- **Easy to use**
  Intuitive interface with simple controls to guide the patient through the test

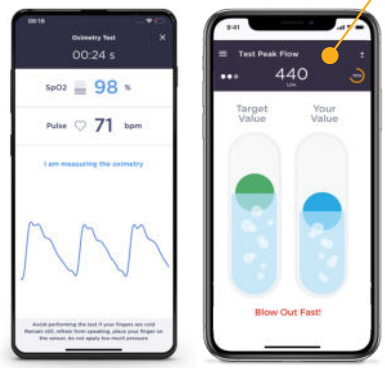
- **All-purpose**
  Designed for screening, home care, and clinical trials

- **Optional SVC measurement with dedicated parameters**
  (EVC, IVC, IC, SET, SIT)

- **App-based**
  Secure storage of tests within the app, allowing for easy and fast sharing of results (PDF and CSV)

- **Pair & Play**
  Pairing between spirometer and app via Bluetooth

- **SpO2% reflectance sensor (touch)**
  Measurement of blood oxygen levels (SpO2%) and heart rate (BPM)



An independent study conducted a comparison of the measurements of **FEV1**, **FVC**, **FEF2575**, and **PEF** obtained from the **Spirobank Smart** with those from hospital-grade devices, demonstrating its high level of accuracy.

Read the full article

Compatible turbines

		Mouthpiece	Turbine Disinfection	Turbine Calibration	Pack	Antiviral Filter
Reusable Turbine		Included Reusable	Not required	Not required	Individually sealed 1 unit/box	Not required
Disposable turbine		Included Disposable	Not required	Not required	Individually sealed 60 or 10 unit/box	Not required

MIR SPIROBANK App

Free dedicated app
designed for **Spirobank Smart** and **Spirobank Oxi**

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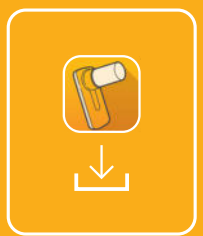
Anytime, anywhere

The advantage of a **smart** device is its connection to the app. **MIR SPIROBANK** is available for free download on the Play Store and App Store.
The MIR SPIROBANK app offers **ease of use**, **secure** and **organized data storage**, and **simple** and **fast sharing** of test results with your doctor for timely and personalized management of the disease.

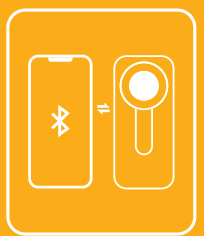
- **Sharing test results in PDF or CSV format** with healthcare professionals via **email**, **WhatsApp**, **SMS**, **Cloud**, **Drive**, **Bluetooth**, **AirDrop**, and other apps
- View and storage of **spirometry** and **oximetry** test results in the app
- Draft of a **personalized electronic diary** with options to set symptoms and add notes for each test
- Tracking and monitoring of **values over time**, with filtering options by day, week, month, or year

Instructions for use

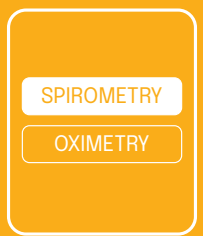
Spirometry and **Oximetry** tests in 5 easy steps!



1. Download the MIR SPIROBANK app



2. Connect the Spirometer to the app via Bluetooth



3. Select in the app the test you want to perform

4. Perform the test

5. View the result and share it with your doctor

Parameters

Spirobank Smart is designed to measure a wide range of parameters.
The app offers an essential selection for a **quick** and **immediate view** of key data (**Default parameters**).

	Spirometry	Oximetry
Spirobank Smart	**Defualt parameters:** FVC, FEV1, FEV1/FVC, PEF, FEF2575, FEV6	–
	Parameters displayed on the PDF report: FVC, FEV1, FEV1/FVC, PEF, FEF2575, FEF25, FEF50, FEF75, PEFTime, EVol, FEV66	–
Spirobank Oxi	**Defualt parameters:** FVC, FEV1, FEV1/FVC, PEF, FEF2575, FEV6	SpO2%min, SpO2%mean, SpO2%max, BPMmin, BPMmean, BPMmax, Ttotal
	Parameters displayed on the PDF report: FVC, FEV1, FEV1/FVC, PEF, FEF2575, FEF25, FEF50, FEF75, PEFTime, EVol, FEV66	SpO2%min, SpO2%mean, SpO2%max, BPMmin, BPMmean, BPMmax, Ttotal

Additional parameters can be displayed through dedicated software developments (**integration with Remote Patient Monitoring systems or third-party apps**).

Additional parameters:
PEF, FEV1, FVC, FEF2575, FEV6, EVOL, PEFTIME, FEV1/FVC %, FEF75, FET, FEF25, FEF50, FIVC, FIV1, PIF, FEV3, FEV05, FEV075, FEV2, FEF7585, FIF25, FIF50, FIF75, FEV1/FEV6%, FEV6/FVC%, FIV1/FIVC%, FEV3/FVC%, FEV05/FVC%, FEV075/FVC%, FEV2/FVC%, EVC, IVC, IC, SET, SIT

Integration

The distinctive feature of Spirobank Smart is its ability to integrate efficiently with Remote Patient Monitoring systems.

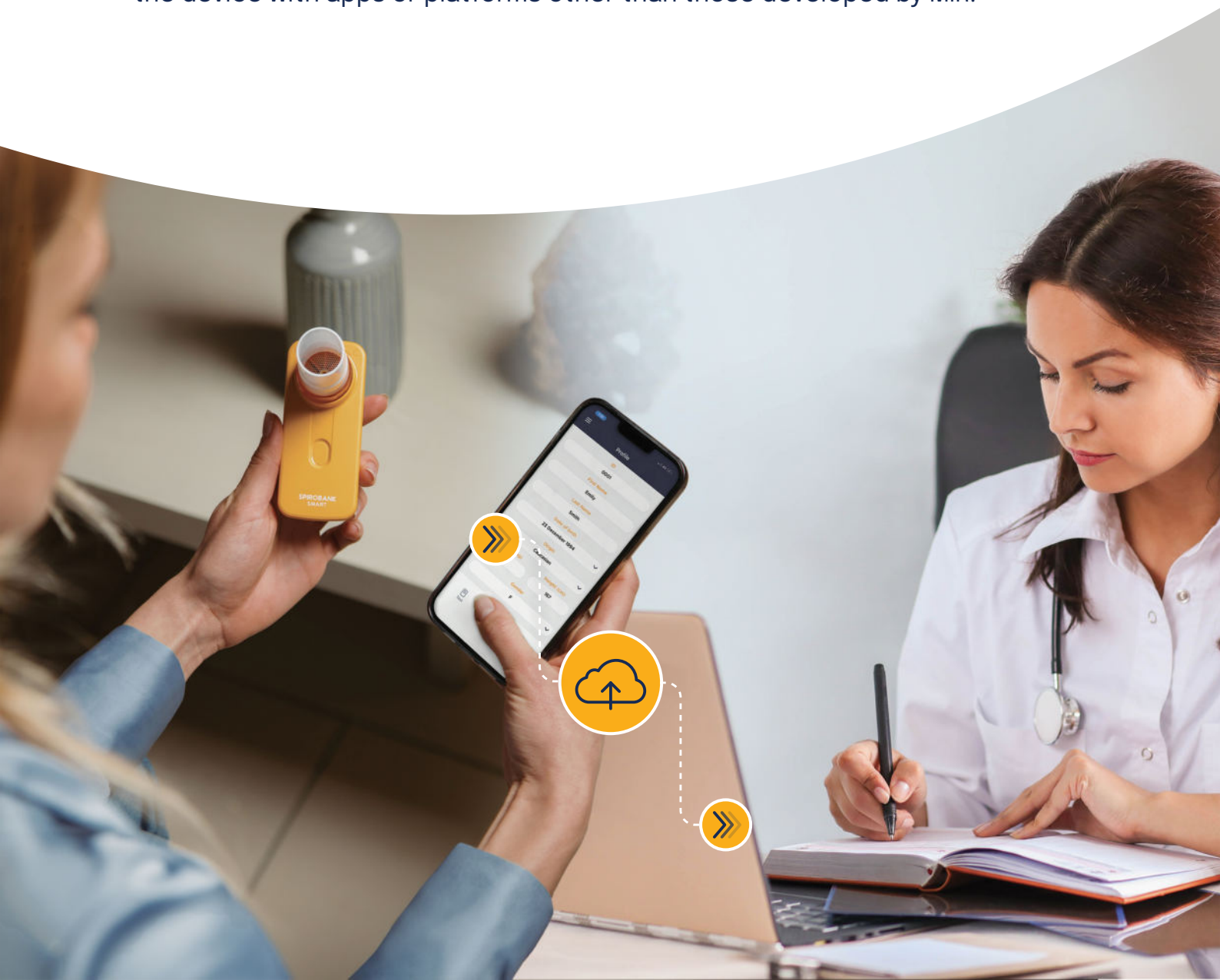
MIR offers two integration solutions tailored to different needs:

1. **DDS (Data Delivery Service)**: Ideal for those who want to use the MIR SPIROBANK app in combination with the device for remote patient monitoring.

   With this service, data measured by Spirobank Smart and collected in the MIR SPIROBANK app are transferred to the customer's remote platform.

   For customers who do not yet have a platform and wish to develop one, MIR provides the necessary specifications, documentation, and support.

2. **SDK (Software Development Kit)**: Ideal for those who prefer to integrate the device with apps or platforms other than those developed by MIR.



Datasheet
Spirobank Smart

cod. 911105xx

Dimensions	49 x 109 x 21 mm
Weight	60.7 g (batterie incluse)
Turbine	Reusable Turbine with plastic Mouthpiece (code 910013)
Power supply	2 batteries AAA 1.5 V
Consumption	max 12 mA Stand by 8 µA
Backup battery voltage	none
Batteries charger	none
Lifetime	5 years
Connectivity	Bluetooth 5.0 ready
Mouthpieces	Ø 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	Temp: MIN -25 °C, MAX+70°C Humidity: MIN 10% RH; MAX 93%RH
Operating Conditions	Temp: MIN +5 °C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH
Shipping conditions	Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH

Spirometry	
Flow sensor	bi-directional digital turbine
Flow range	±16L/s
Volume accuracy	±2.5% o 0.05 L
Flow accuracy	±5% o 0.20 L/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	none
Test available	FVC, VC
Measured parameters	FEV1, PEF, FVC, FEV6, FEV2575, FVC2575
Additional parameters	FEF75, FEF2575, FET, FEV1%, FEV6%, FEV6/FVC, FEF25, FEF50, Vext, FIVC, FIV1, FIV1%, PIF, FEV3, FEV3%, PEF Time, FEV05, FEV05%, FEV075, FEV075%, FEV2, FEV2%, FEF7585, FIF25, FIF50, FIF75, EVC, IVC, IC, SET, SIT
Memory capacity	The application on the smart phone memorizes data

Certificates & Registrations	
CE 0476	MDR 2017/745
FDA 510(k)	K230501
Health Canada	71191 (class II)
EMDN liv.4	Z121501
CND code	Z12150102
GMDN code	46906
Applicable standards	IEC 60601-1:2005 + A1:2012 + A2:2020 IEC 60601-1-2:2014 + A1:2020 EN ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive EN ISO 15223-1:2021 IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-11:2015 + A1:2020 ATS/ERS Guidelines (2019 update) ISO 26782:2009 ISO 23747:2015

Datasheet Spirobank Oxi

cod. 911125xx

Dimensions	49 x 109 x 21 mm
Weight	60.7 g (batterie incluse)
Turbine	Reusable Turbine with plastic Mouthpiece (910013)
Mouthpiece	Ø 30 mm (1.18 inches)
Power supply	2 batteries AAA 1.5 V
Consumption	max 20 mA Stand by 8 µA
Lifetime	5 years
IP protection level	IP22
Connectivity	Bluetooth® 5.0 ready
Type of electrical protection	Internally powered
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage conditions	Temp: MIN -25 °C, MAX+70°C Humidity: MIN 10% RH; MAX 93%RH
Operating Conditions	Temp: MIN +5 °C, MAX +40 °C Humidity: MIN 15% RH; MAX 93%RH
Shipping conditions	Temp: MIN -25°C, MAX +70 °C Humidity: MIN 10% RH, MAX 93%RH

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, VC
Measured parameters	FEV1, PEF, FVC, FEV6, FEV2575, FVC2575
Additional optional parameters	FEF75, FEF2575, FET, FEV1%, FEV6%, FEV6/FVC, FEF25, FEF50, Vext, FIVC, FIV1, FIV1%, PIF, FEV3, FEV3%, PEF Time, FEV05, FEV05%, FEV075, FEV075%, FEV2, FEV2%, FEF7585, FIF25, FIF50, FIF75, EVC, IVC, IC, SET, SIT
Memory capacity	The application on the remote device (smartphone/tablet) memorizes data

Oximetry

Measuring method	Double wavelength
%SpO2 range	70%-100%
%SpO2 accuracy	±1.9%
Average number of beats for the %SpO2 calculation	12 beats
Pulse Rate range	30-200 BPM
Pulse Rate accuracy	±3%
Average interval for Pulse rate calculation	12 seconds
Quality signal indicator	0-8 lines
Available tests	spot
Measured parameters	%SpO2MIN, %SpO2MEAN, %SpO2MAX, BPMMIN, BPMMEAN, BPMMAX TTOTAL
Wavelength sensors	Red 660 nm Infrared 880 nm
Maximum optical output power	1.2 mW

Certificates & Registrations

CE 0476	MDR 2017/745
FDA 510 (k)	K230501
Health Canada	107185 (class II)
EMDN/GND	Z12150102 Z1203020408
GMDN Code	46906 45607
Applicable standards	ATS/ERS 2005, 2019 Update ISO 26782:2009 ISO 23747:2015 ISO 14971:2019 ISO 10993-1:2018 2011/65/UE Directive 2015/863/UE Directive EN ISO 15223-1:2021 IEC 60601-1:2005 + A1:2012 + A2:2020 EN 60601-1-2:2015 + A1:2021 EN IEC 60601-1-6:2010 + A1:2013 + A2:2020 EN 60601-1-11:2015 + A1:2020 ISO 80601-2-61:2017

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