



# Spirobank II Smart



**Multiplatform portable  
spirometer for Tablets and PCs:  
3 modes of use in a single device**

# Supported tests

**Spirometry:** FVC, VC, MVV, PRE/POST bronchodilator comparison

**Oximetry (optional):** Spot test (SpO2%, BPM)

## Key features

### Dedicated app

Bluetooth connection to Tablet via dedicated **MIR Spiro** app

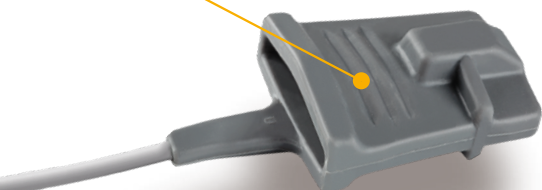


### 3 Modes of use

- Stand Alone
- PC via USB (**MIR Spiro** software)
- Tablet via Bluetooth (**MIR Spiro** app)

### SpO2% Sensor

Oximetry sensor to detect blood oxygen saturation



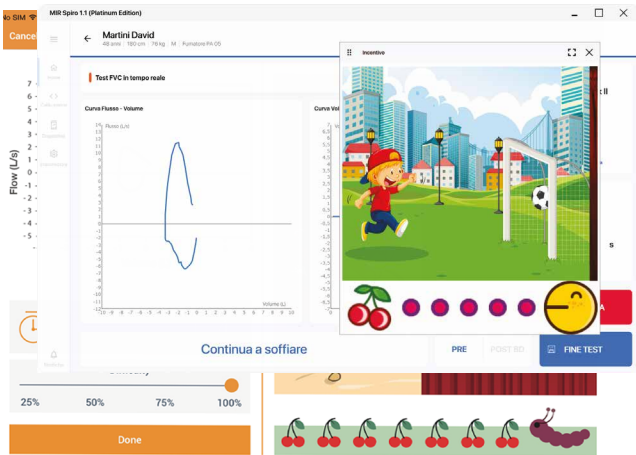
### Display

Intuitive display with easy-to-use buttons

## Real-time tests

Real-time tests displayed on the Tablet and PC screen

## Pediatric incentive



Real-time animation available on both Tablet and PC for improved patient collaboration during the test

## Integrated temperature sensor

Automatic BTPS Conversion

## Long-lasting rechargeable battery

Rechargeable lithium battery

## Large internal memory

Storage up to 10,000 spirometric tests or 500 hours of oximetry



## Predicted values

Wide selection of predicted values including GLI, ERS and others, directly on the device, Tablet and PC

## EMR/EHR connectivity

Integration via **MIR Spiro** software and **MIR Spiro** app with EMR/EHR (in HL7, GDT, FHIR, EXCHANGE PROTOCOL)

# Compatible turbines

		Mouthpiece	Turbine disinfection	Turbine calibration	Packaging	Antiviral filter
FlowMIR® disposable turbine		Disposable included	Not required	Not required	Individually packaged: packs of 60 pieces	Optional
Reusable turbine		Required, not included	Required	Required	Pack of 1 unit	Recommended by ATS

# How to use

Spirobank II Smart works in **Stand Alone** mode,  
connected to **PC via USB**  
and connected to **Tablet via Bluetooth**

## MIR Spiro software

- \\ Comprehensive software for spirometry and oximetry
- \\ Designed to be integrated with EMR/EHR
- \\ Complies with the latest ATS/ERS guidelines
- \\ Available for desktop and laptop use
- \\ MacOS and Windows

All MIR professional devices  
work with **MIR Spiro** software,  
**the latest generation software**  
for spirometry and oximetry.



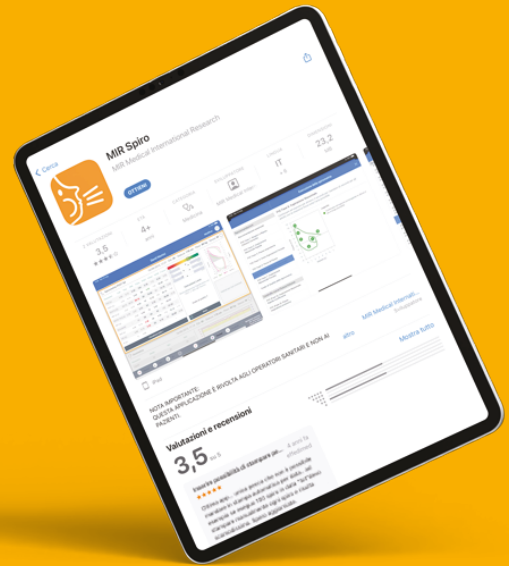
## Platinum Card

To subscribe to a Platinum  
subscription plan  
it is necessary to **have**  
**the MIR Spiro Platinum Card.**

# MIR Spiro app

Intuitive and flexible interaction during spirometry procedures!

- \ Real-time tests
- \ Pediatric incentive
- \ Virtual Assistant
- \ iOS and Android



## Measured parameters

	From MIR Spiro software via connection to the device	From MIR Spiro app via connection to the device	From device in Stand Alone mode
<b>Spirometry</b>	FVC, FEV1, PEF, FEF75, FEF25-75, FET, FEV1/FVC, FEV6, FEV1/FEV6, FEF25, FEF50, FIVC, FEV1/VC, ELA, MVV(cal), Time to PEF, FEV0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEF75-85, Extr. Vol, VC, EVC, IVC, IC, VC, ERV FEV3, FIV1, FIV1/FIVC, PIF, FEV3/FVC, PIF, FEV2, FEV2/FVC, FIF25, FIF50, FIF75, R50, FEV1/PEF (EI), FEV1/FEV0.5 (RFEV), TV, VE, RR, tl	FVC, FEV1, FEV1%, PEF, ELA, FEF25-75, FET, FEF50*, FIVC* *Available on Android Tablet only	*FVC, *FEV1, *PEF, FVC, FEV1, FEV1/FVC, FEV1/VC, PEF, T-PEF, FEF25-75, FEF75-85, FEF25, FEF50, FEF75, FEV0.5, FEV0.5%, FEV0.75, FEV0.75%, FEV2, FEV2%, FEV3, FEV3/FVC, FEV6, FEV6%, FET, BEV, FIVC, FIV1, FIV1/FIVC, PIF, FIF25, FIF50, FIF75, R50, MVVcal, VC, EVC, IVC, IC, ERV, TV, VE, RR, tl, tE, TV/tl, tl/tTot, MVV, ELA *Best values
<b>Oximetry (optional)</b>	SpO2% [Min, Max, Media], BPM [Min, Max, Media]	SpO2% [Min, Max, Media], BPM [Min, Max, Media]	SpO2% [Min, Max, Media], BPM [Min, Max, Media]

# Datasheet

code 911028xx (spirometer)  
code 911029xx (spirometer + oximeter)

<b>Size</b>	55 x 160 x 25 mm
<b>Weight</b>	140 g (battery pack included)
<b>Turbine</b>	· Reusable Turbine (code 910002) · Disposable turbine (code 910004)
<b>Power supply</b>	3.7 V, 1100 mAh Lithium-Ion Rechargeable
<b>Current</b>	1100 mAh
<b>Consumption</b>	~20-30 mA (during testing)
<b>Charge Batteries</b>	Voltage=5 V DC, Current = minimum 500 mA, Connector: micro USB type B Complies with EN 60601-1
<b>Autonomy</b>	50 hours
<b>Connectivity</b>	USB 2.0, Bluetooth® 4.0
<b>Display</b>	monochrome LCD, 160 x 80 pixels
<b>Keyboard</b>	6-key membrane
<b>Mouthpiece</b>	Ø 30 mm (1.18 in)
<b>Type of electrical protection</b>	Powered internally
<b>Safety level Electric shock</b>	Type BF device
<b>IP protection level</b>	IPX1
<b>Terms of use</b>	Device for continuous use
<b>Storage conditions</b>	Temp: MIN -20°C, MAX+60°C Humidity: MIN 10% RH; MAX 95%RH
<b>Operating conditions</b>	Temp: MIN +10°C, MAX +40°C Humidity: MIN 10% RH, MAX 95%RH
<b>Transport conditions</b>	Temp: MIN -40°C, MAX +70°C Humidity: MIN 10% RH, MAX 95%RH

<b>Spirometry</b>	
<b>Sensor</b>	two-way digital turbine
<b>Flow range</b>	±16L/s
<b>Volume accuracy</b>	±2.5% or 50mL
<b>Flow accuracy</b>	±5% or 200 mL/s
<b>Dynamic resistance</b>	<0.5 cm H2O/L/s
<b>Temperature sensor</b>	semiconductor (0-45°C)
<b>Available tests</b>	FVC, VC, IVC, MVV, PRE-POST
<b>Measured parameters</b>	FVC, FEV1, FEV1/FVC%, TPEF, FEV 0.5, FEV0.5/FVC%, FEV0.75, FEV0.75/FVC%, FEV2, FEV2/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25, FEF50, FEF75, FEF25-75, FEF75-85%, FET, Vext, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC%, FIF25, FIF50, FIF75, R50, PIF, IRV, VC, IVC, EVC, IC, ERV, FEV1/VC%, TV, VE, RR, tl, tE, tl/t-tot, TV/tl, MVV, MVV cal
<b>Memory capacity</b>	more than 10,000 tests
<b>Oximetry (on request)</b>	
<b>Measurement method</b>	Red and infrared absorption
<b>SpO2% range</b>	0-99%
<b>Accuracy of SpO2%</b>	± 2% between 70-99% SpO2
<b>Average number of beats for SpO2% calculation</b>	8 beats
<b>Heart Pulse Range</b>	30-300 BPM
<b>Cardiac pulse accuracy</b>	± 2BPM or 2% the greater of the two
<b>Mean interval for calculation of heartbeat</b>	8 seconds
<b>Signal quality indication</b>	0 - 8 segments on screen
<b>Test available</b>	spot
<b>Measured parameters</b>	SpO2% min, max, average Min, Max, Avg BPM Test duration % Duration of bradycardia (<40 BPM) % Duration of tachycardia (>120 BPM) % Time with SpO2 ≤ 90% (T90%, T89%)
<b>Memory capacity</b>	about 300 hours of oximetry

<b>Certificates and registrations</b>	
<b>CE 0476</b>	MDR 2017/745
<b>FDA 510 (k)</b>	K 061712
<b>Health Canada</b>	71191 (class II), 75535 (class III)
<b>EMDN liv.4</b>	Z121501
<b>CND Code</b>	Z12150102 (spiral) Z1203020408 (spiro + oxi)
<b>GMDN Code</b>	46906 (spiro), 45607 (spiro + oxi)
<b>List no</b>	2494356/R (911028I0) 2494363/R (911028I1) 2494457/R (911029I0) 2494606/R (911029I1)
<b>Applicable regulations</b>	Electrical Safety IEC 60601-1 Electro Magnetic Compatibility EN 60601-1-2 ISO 80601-2-61:2017 ISO 26782: 2009 ISO 23747: 2015 ATS/ERS:2005, 2019(update) IEC 60601-1-6:2010 IEC 60601-1-8:2006+ AMD1:2012 IEC 60601-1-9:2007+AMD1:2013 IEC 62304:2006 + A1:2015 ISO 10993-1:2018 Directive 2014/53/EU RED

## **Compliance with guidelines and standards**

**Spirometry:** ATS/ERS 2005 + update 2019;

ISO 23747: 2015; ISO 26782: 2009

**Oximetry:** ISO 80601-2-61:2017

**DISTRIBUÍDO POR:**

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