

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

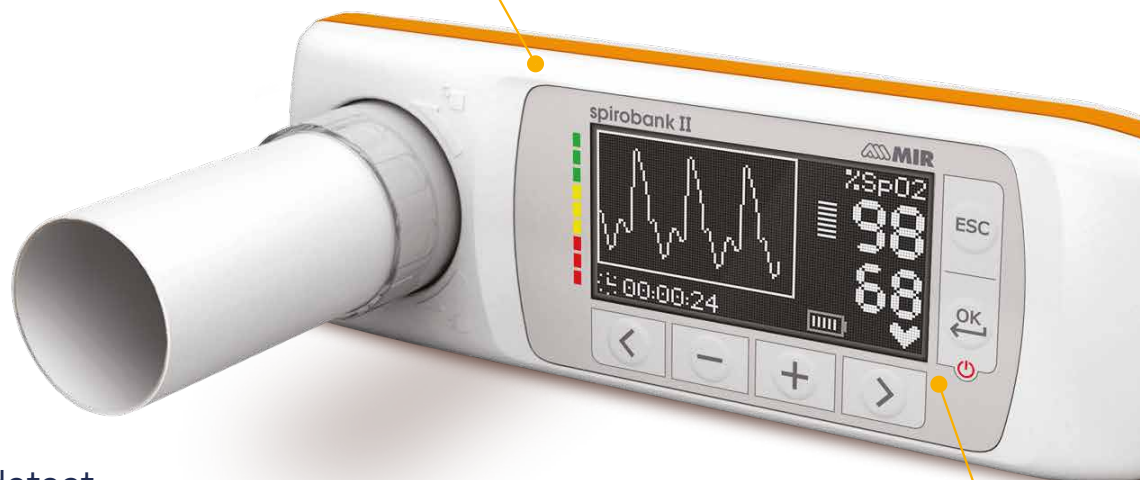
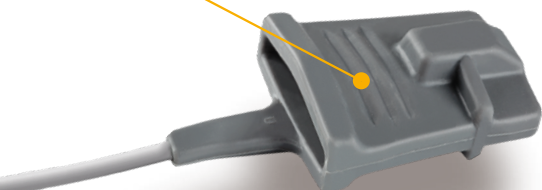


3 Modes of use

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

SpO2% Sensor

Oximetry sensor to detect blood oxygen saturation



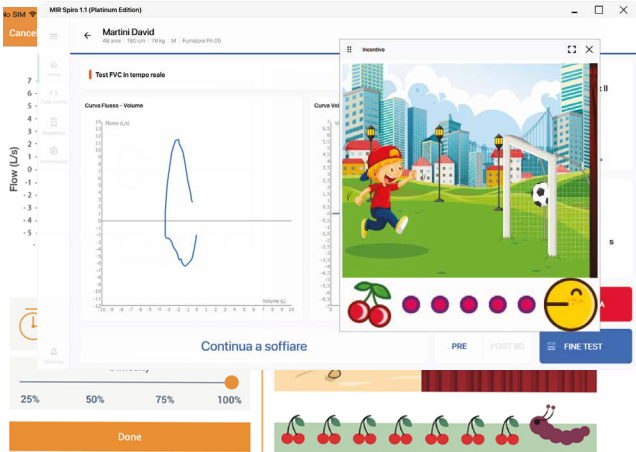
Display

Intuitive display with easy-to-use buttons

Real-time tests

Real-time tests displayed on the device screen, Tablet, and PC

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)

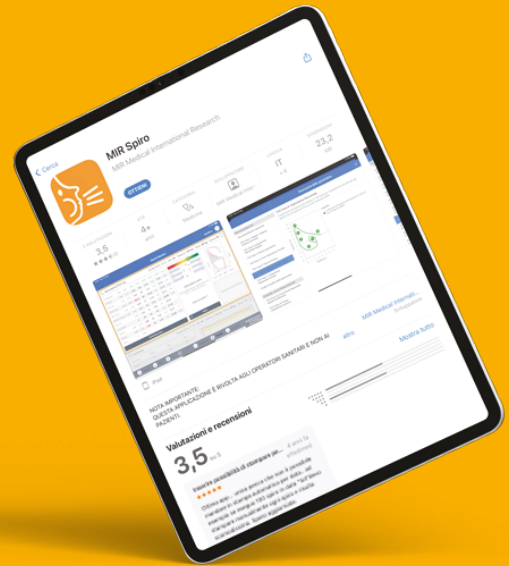
Compatible turbines

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

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
Spirometry	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
Oximetry (optional)	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)

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

Spirometry	
Sensor	two-way digital turbine
Flow range	±16L/s
Volume accuracy	±2.5% or 50mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)
Available tests	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	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
Memory capacity	more than 10,000 tests
Oximetry (on request)	
Measurement method	Red and infrared absorption
SpO2% range	0-99%
Accuracy of SpO2%	± 2% between 70-99% SpO2
Average number of beats for SpO2% calculation	8 beats
Heart Pulse Range	30-300 BPM
Cardiac pulse accuracy	± 2BPM or 2% the greater of the two
Mean interval for calculation of heartbeat	8 seconds
Signal quality indication	0 - 8 segments on screen
Test available	spot
Measured parameters	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%)
Memory capacity	about 300 hours of oximetry

Certificates and registrations	
CE 0476	MDR 2017/745
FDA 510 (k)	K 061712
Health Canada	71191 (class II), 75535 (class III)
EMDN liv.4	Z121501
CND Code	Z12150102 (spiral) Z1203020408 (spiro + oxi)
GMDN Code	46906 (spiro), 45607 (spiro + oxi)
List no	2494356/R (911028I0) 2494363/R (911028I1) 2494457/R (911029I0) 2494606/R (911029I1)
Applicable regulations	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