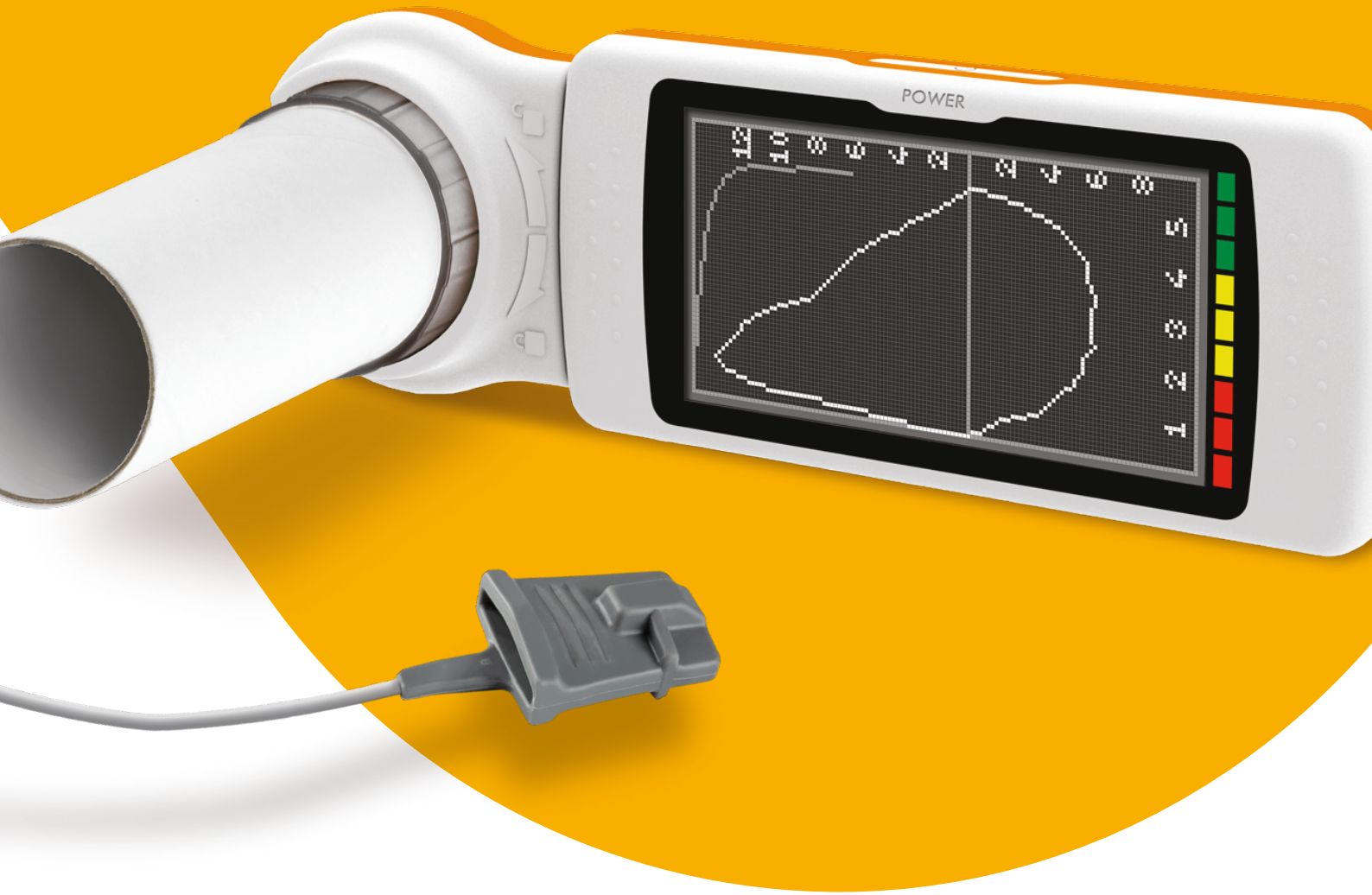
MIR

Spirodoc



Touchscreen portable spirometer with optional 3D oximeter: 6MWT, Sleep Test, and 24h Holter for SpO2%

Available configurations

Spirodoc is available
in 3 configurations:

Spirometer

Spirometer + Oximeter

Oximeter

Supported tests

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

Oximetry (optional): Spot test (SpO2%, BPM), 6MWT, Sleep test, and 24h Holter for SpO2%

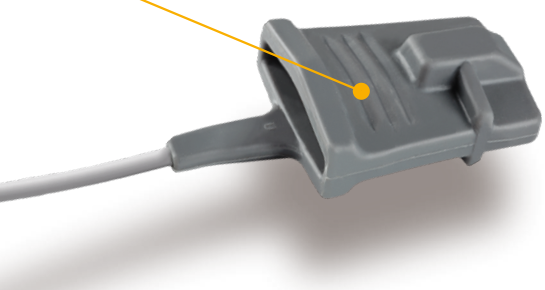
Key features

Multifunctional
In addition to spirometric and oximetric spot tests, Spirodoc also makes it possible to perform 6MWT, Sleep Test, and 24h Holter Test with the 3D oximetry option

Touchscreen
Touchscreen for fast data entry

Optoelectronic reader for removable spirometry
Available in Spirometer and Spirometer + Oximeter configurations to facilitate oximetry testing

3D Oximetry: 6MWT, Sleep Test, and 24h Holter for SpO2%
Measurement of desaturation events during exercise, sleep and daily activities

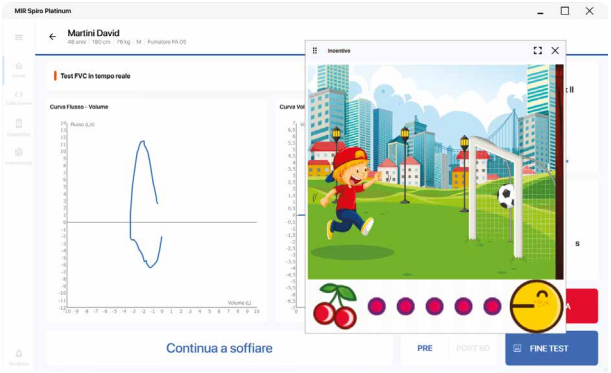


Triaxial accelerometer
(with 3D oximeter)
Triaxial accelerometer for recording patient movement and position during measurement

Real-time tests

Real-time tests displayed on the device and PC screen

Pediatric incentive



Real-time animation available on **MIR Spiro** software, for improved patient collaboration during the test

Integrated temperature sensor

Automatic BTPS Conversion

Long-lasting rechargeable battery

Long-lasting rechargeable lithium battery for extended autonomy in Stand Alone mode

Predicted values

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

EMR/EHR connectivity

Integration via **MIR Spiro** software 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

How to use

Spirodoc works both in **Stand Alone** mode
and connected to the **PC via USB cable**

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.

*provided with all MIR professional devices, available for purchase online (mymir.spirometry.com) or from your trusted MIR distributor

Measured parameters

	From MIR Spiro software 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, tI	*FVC, *FEV1, *PEF, FVC, FEV1, FEV1/FVC, FEV1/VC, PEF, FEF25-75, FEF25, FEF50, FEF75, FEV3, FEV3/FVC, FEV6, FEV6%, FET, BEV, FIVC, FIV1, FIV1/FIVC, PIF, MVVcal, VC, EVC, IVC, IC, ERV, TV, VE, RR, tI, tE, TV/tI, tI/tTOT, MVV, ELA *Best values
Oximetry (optional)	SpO2% [Baseline, Min, Max, Mean], BPM [Baseline, Min, Max, Mean], T Total, T Analysis, T<90%, T<89%, T<88%, T<87%, EvSpO2%<89, Δ Index, t<40BPM, t>120BPM, Ev<40BPM, Ev>120BPM, SpO2% End, BPM End, SpO2% Start, BPM Start, T Walk, T Recovery, Distance, T2%Δ SPO2, T4%Δ SPO2, Theoretical, Theoretical min, Theoretical %, Theoretical min, AUC/Distance*, Dyspnea Start, Dyspnea Fin, Dyspn CHG, Diastolic Start, Systolic Start, Diastolic End, Systolic End, Steps, VMU**, O2-GAP***, O2, ODI Average Desat., Tot Desatur., Max Duration, Peak Desatur., BPM Index, Average Desat., Average Fall, Max Fall, BPM Change, NOD4%, NOD89%, NOD90%, t.NOD4%, t.NOD89%, t.NOD90%	SpO2% [Baseline, Min, Max, Mean], BPM [Baseline, Min, Max, Mean], T Total, T Analysis, T<90%, T<89%, T<88%, T<87%, EvSpO2%<89, Δ Index, t<40BPM, t>120BPM, Ev<40BPM, Ev>120BPM, SpO2% End, BPM End, SpO2% Start, BPM Start, T Walk, T Recovery, Distance, T2%Δ SPO2, T4%Δ SPO2, Theoretical, Theoretical min, Theoretical %, Theoretical min, AUC/Distance*, Dyspnea Start, Dyspnea Fin, Dyspn CHG, Diastolic Start, Systolic Start, Diastolic End, Systolic End, Steps, VMU**, O2-GAP***, O2, ODI Average Desat., Tot Desatur., Max Duration, Peak Desatur., BPM Index, Average Desat., Average Fall, Max Fall, BPM Change, NOD4%, NOD89%, NOD90%, t.NOD4%, t.NOD89%, t.NOD90%

Datasheet

code 911080xx (spiro) code 911081xx (spiro+oxy)

Main body	
Size	48 x 101 x 16 mm
Weight	99 g (battery included)
Turbine housing	
Size	47 x 46 x 24 mm
Weight	17 g (battery included)
Turbines	• Reusable turbine (code 910002) • Disposable turbine (code 910004)
Accelerometer	triaxial accelerometer
Power supply	3.7V lithium-ion battery, 1100 mAh 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® 2.1
Display	monochrome LCD, 160 x 80 pixels Size 2.8 inches
Keyboard	Touchscreen
Mouthpiece	Ø 30 mm (1.18 inches)
Type of electrical protection	Powered internally
Safety level	Type BF device
Against shock	
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
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

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)
Measured parameters	FVC, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25%, FEF50%, FEF75%, FEF25-75%, FET, Vext, ELA, FIVC, FIV1, FIV1/FIVC%, PIF, VC, IVC, EVC, IC, ERV, FEV1/VC%, VT, VE, RR, ti, te, ti/t-tot, VT/ti, MVV
Memory capacity	more than 10,000 tests
Oximetry (on request)	
Measurement method	Infrared absorption
SpO2% Range	0-99%
Accuracy of SpO2%	± 2% between 70-99% SpO2
Average number of beats for SpO2% calculation	8 beats
Cardiac pulse range	30-254 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
Measured parameters	
For each test	SpO2%MIN, SpO2%MEAN SpO2%MAX, BPM MIN, BPMMEAN, BPM MAX, Ttotal, Tanalysis, T<90%, T<89%, T<88%, T<87%, EvSpO2%<89, ΔIndex, T<40BPM, T>120BPM, Ev<40BPM, Ev>120BPM
Sleep Test	SpO2%BASE, BPMBASE, ODI, Mean Dur. Desat., TotDesaturat., Longest Desat., Desatur. Peak, BPM Index, Mean Desaturat., Mean Drop, Max Drop, BPM Variation, NOD4%, NOD89%, NOD90%, t.NOD4%, t.NOD89%, t.NOD90% Record of body position

6MWT Test	SpO2% start, SpO2% end, BPM start,BPM end, SpO2% base, Tbaseline, Twalking, Trecovery, Distance, T2%ΔSPO2, T4%ΔSPO2, Predicted, %Predicted, Predicted min, %Predicted min AUC/Distance, Dyspnea, Dyspnea base, Dyspnea end, Dyspnea CHG, Fatigue base, Fatigue end, Fatigue CHG, Diastolic base, diastolic end, Systolic base, Systolic end, Steps, VMU, O2-GAP, O2
Memory capacity	about 300 hours of oximetry
Certificates and registrations	
CE 0476	MDR 2017/745
FDA 510 (k)	K 103530
Health Canada	71191 (class II), 75535 (class III)
EMDN liv.4	Z121501
CND Code	Z12150102 (spiral) Z1203020408 (spiro + oxy)
GMDN Code	46906 (spiral), 45607 (spiro + oxy)
Ministry of Health	2493989/R (910600) 2494292/R (910606) 2494301/R (910610) 2494198/R (910600I1) 2494295/R (910606I) 2494319/R (910610I1) 2494380/R (910600I0) 2494386/R (910610I0)

Compliance with guidelines and standards

Spirometry: ATS/ERS 2005 + update to 2019;
ISO 23747: 2015; ISO 26782: 2009
Oximetry: ISO 80601-2-61:2017

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