



# 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

### Touchscreen

Touchscreen for fast data entry

### 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



### 3D Oximetry: 6MWT, Sleep Test, and 24h Holter for SpO2%

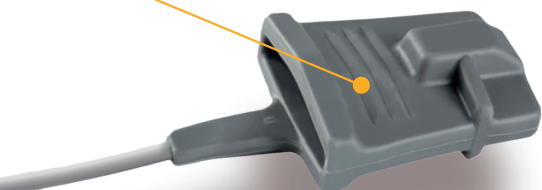
Measurement of desaturation events during exercise, sleep and daily activities

### Optoelectronic reader for removable spirometry

Available in Spirometer and Spirometer + Oximeter configurations to facilitate oximetry testing

### Triaxial accelerometer (with 3D oximeter)

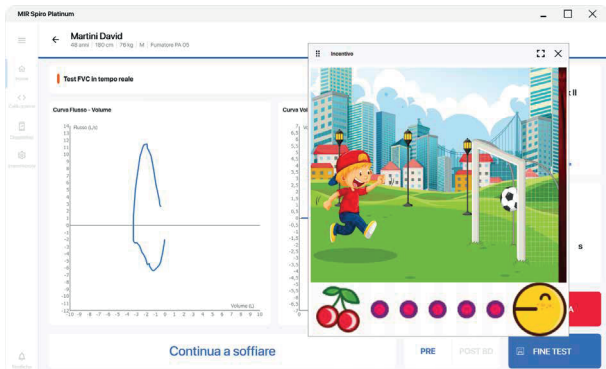
Triaxial accelerometer for recording patient movement and position during measurement



## Real-time tests

Real-time tests displayed on the 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
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.**



# Measured parameters

	From MIR Spiro software 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, 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
<b>Oximetry (optional)</b>	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)

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

<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>Measured parameters</b>	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
<b>Memory capacity</b>	more than 10,000 tests
<b>Oximetry (on request)</b>	
<b>Measurement method</b>	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>Cardiac pulse range</b>	30-254 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>Measured parameters</b>	
<b>For each test</b>	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
<b>Sleep Test</b>	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

<b>6MWT Test</b>	SpO2% start, SpO2% end, BPM start,BPM end, SpO2% base, Tbaseline, Twalking, Trecovey, Distance, T2%ΔSP02, T4%ΔSP02, 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
<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 103530
<b>Health Canada</b>	71191 (class II), 75535 (class III)
<b>EMDN liv.4</b>	Z121501
<b>CND Code</b>	Z12150102 (spiral) Z1203020408 (spiro + oxy)
<b>GMDN Code</b>	46906 (spiral), 45607 (spiro + oxy)
<b>Ministry of Health</b>	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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