



**Technical specification**

<b>Width</b>	220 mm
<b>Length</b>	210 mm
<b>Thickness</b>	51 mm
<b>Weight</b>	1450 g (battery pack included)

**Sensors**



miniflowmeter (code 900595)  
for reusable and disposable turbine  
dimension (Ø 30 mm, 42 mm)



Reusable soft, adult, MIR sensor for oximetry tests (code 919024) only for spirolab code 911081

<b>Power supply</b>	Rechargeable battery and mains power Ni-MH, 6 elements
<b>Current capacity</b>	4500 mAh
<b>Consumption</b>	average 250 mA
<b>Backup battery voltage</b>	none
<b>Batteries charger</b>	Output voltage=12 V, current=1A, compliant with EN 60601-1

<b>Autonomy</b>	~10 hours
<b>Connectivity</b>	USB 2.0, Bluetooth® 2.1
<b>Display</b>	7 inch colour touch screen LCD Display with 800x480 resolution

<b>Keyboard</b>	absent, touchscreen
<b>Mouthpieces</b>	Ø 30 mm (1.18 inch)
<b>Type of electrical protection</b>	Internally powered Class II while charging battery
<b>Safety level for shock hazard</b>	Type BF Apparatus

<b>Conditions of use</b>	Apparatus for continuous use
<b>Storage conditions</b>	Temperature: MIN -40 °C, MAX +70 °C

<b>Transport conditions</b>	Temperature: MIN -40 °C, MAX +70 °C
	Humidity: MIN 10% RH; MAX 95%RH

<b>Operating conditions</b>	Temperature: MIN + 10 °C, MAX + 40 °C
	Humidity: MIN 10% RH, MAX 95%RH

<b>Applied norms</b>	Electrical Safety EN 60601-1 Electro Magnetic Compatibility EN 60601-1-2
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<b>Degree of protection against water penetration</b>	IPX1 appliance protected against water leaks
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**Codes and equipments**

<b>911080E0</b>	spiro
<b>911080E1</b>	spiro with reusable turbine

<b>911080E2</b>	spiro with 120 FlowMir
<b>911081E0</b>	spiro+oxy
<b>911081E1</b>	spiro+oxy with reusable turbine
<b>911081E2</b>	spiro+oxy with 120 FlowMir

**Spirometry**

<b>Flow sensor</b>	bi-directional digital turbine
<b>Volume rate</b>	10 L
<b>Flow range</b>	±16L/s
<b>Volume accuracy</b>	±2.5% or 50 mL
<b>Flow accuracy</b>	±5% or 200 mL/s
<b>Dynamic resistance</b>	<0.5 cm H <sub>2</sub> O/L/s
<b>Temperature sensor</b>	semiconductor (0-45°C)
<b>Test available</b>	FVC, VC, IVC, MVV, PRE-POST
<b>Measured parameters</b>	FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEF0.5, DTPEF, FEV 0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEV2, FEV2/FVC, FEV3, FEV3/FVC, FEV6, FEV1/FEV6, PEF, FEF25, FEF50, FEF75, FEF2575, FEF7585, FET, Vext, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC, FIF25, FIF50, FIF75, R50, MVVcal, PIF, IRV, VC, EVC, IVC, IC, ERV, IRV, FEV1/VC, TV, VE, RR, ti, te, ti/t-tot, TV/ti, MVV

**Memory capacity**

Up to 10000 tests

**Oximetry (on request)**

<b>Measurement method</b>	Red and infrared absorption
<b>SpO2 range</b>	0-99%
<b>SpO2 accuracy</b>	± 2% between 70-99% SpO2
<b>Average number of heart beats for the %SpO2 calculation</b>	8 beats
<b>Pulse Rate range</b>	18-300 BPM
<b>Pulse Rate accuracy</b>	± 2BPM or 2% whichever is greater
<b>Average interval for the calculation of cardiac pulse</b>	8 seconds

<b>Signal quality indication</b>	0 - 8 segments on display
<b>Test available</b>	spot
<b>Measured parameters</b>	SpO2% min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%, T89%), T5

<b>Memory capacity</b>	about 500 hours oximetry
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**Certificates & Registrations**

<b>CE 0476</b>	MED 9826
<b>FDA 510 (k)</b>	K 052140
<b>Health Canada</b>	71191 (class II)
<b>CND code</b>	Z12150102 (spiro) Z1203020408 (spiro + oxy)
<b>GMDN code</b>	46906 (spiro), 45607 (spiro + oxy)
<b>Ministry of Health</b>	1272475/R (spiro) 1272476/R (spiro + oxy) 1645455/R (spiro)



# Spirolab



**All-in-one Desktop Spirometer**  
for rapid and comprehensive reporting

# Supported tests

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

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

## Key features

### All-in-one

Complete spirometer, all-in-one touchscreen and integrated printer for testing without the need for a computer

### Calibration

Available on device, with calibration report printable by the instrument

### 7" colour touchscreen

Intuitive interface and clear data display

### SpO2% Sensor

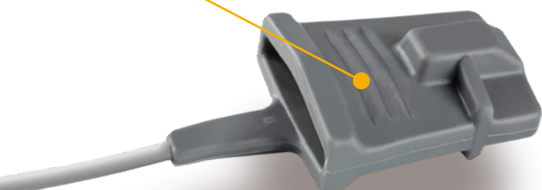
Oximetry sensor to detect blood oxygen saturation

### Connection to external Postscript Printer

### Integrated thermal printer

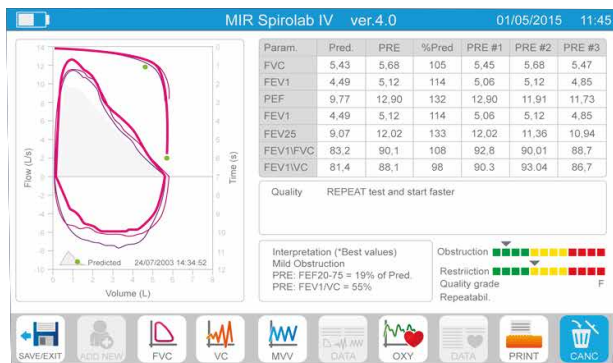
Customizable print and detailed immediate test reports. 80<120 prints with a single roll\*.

(Paper size 112 mm; Paper weight 56g +/- 4 gr/m2)



\*Using non-original MIR paper rolls or heavier than indicated can irreparably damage the printer

## Real-time tests



## Integrated temperature sensor

Automatic BTPS Conversion

## Long-lasting rechargeable battery

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

## Large internal memory

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

## Pediatric incentive



## 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

Spirolab works both in **Stand Alone** mode and connected to **PC via USB**

## 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

	<b>From MIR Spiro software via connection to the device</b>	<b>From device in Stand Alone mode</b>
<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	VC, FEV1, FEV1/ FVC, FEV1/VC, PEF, FEF25, FEF50, FEF75, FEF25-75, FEF75-85, ELA, extrapolated Vol, FET, Time to PEF, FEV0.5, FEV0.5/FVC, FEV0.75, FEV0.75/ FVC,FEV2, FEV2/ FVC, FEV3, FEV3/ FVC, FEV6, FEV1/ FEV6, FEV1/PEF, FEV1/FEV0. 5, FIVC, FIV1, FIV1/FIVC, PIF, FIF25, FIF50, FIF75, FEF50/FIF50, VC, IVC, IC, ERV, IRV, Rf, VE, VT, tI, tE, VT/tI, tE/tTOT, MVV (measured), MVV (calculated)
<b>Oximetry (optional)</b>	SpO2% [Baseline, Min, Max, Mean], Wrist Rate [Baseline, Min, Max, Mean], T90, T89, T88, T5, Index [12s], SpO2% Events, Wrist Rate Events [bradycardia, tachycardia], Tot Time, Measured Time	SpO2% [Baseline, Min, Max, Mean], Wrist Rate [Baseline, Min, Max, Mean], T90, T89, T88, T5, Index [12s], SpO2% Events, Wrist Rate Events [bradycardia, tachycardia], Tot Time, Measured Time

# Datasheet

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

Size	220 x 210 x 51 mm
Weight	1450 g (battery pack included)
Sensors	<ul style="list-style-type: none"> <li>· For reusable and disposable miniflowmeter turbines (code 910595)</li> <li>· For spirolab code 911081 only Reusable soft adult sensor for oximetry test (code 919024)</li> </ul>
Power supply	Ni-MH rechargeable battery pack, 6 elements
Current	4500 mAh
Consumption	medium 250 mA
Backup battery voltage	absent
Charge Batteries	output voltage=12 V, current=1A, compliant with EN 60601-1
Autonomy	~ 10 hours
Connectivity	USB 2.0, Bluetooth® 5
Display	7 inch colour touchscreen resolution 800x480 pixels LCD
Keyboard	absent, touchscreen
Mouthpiece	Ø 30 mm (1.18 inches)
Type of electrical protection	Internally powered Class II while battery is charging
Safety level due to shock hazard	Type BF device
Terms of use	Device for continuous use
Storage conditions	Temp: MIN -40°C, MAX +60°C Humidity: MIN 10% RH; MAX 95%RH
Transport conditions	Temp: MIN -40°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
Degree of protection against water penetration	IPX1
<b>Spirometry</b>	
Sensor	two-way digital turbine
Volume range	10 L
Flow range	±16L/s
Volume accuracy	±2.5%o50mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)

<b>Available tests</b>	FVC, VC, IVC, MVV, PRE-POST
<b>Measured parameters</b>	FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEV0.5, PEF Time, FEV 0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEV2, FEV2/FVC, FEV3, FEV3/FVC, FEV6, FEV1/FEV6, PEF, FEF25, FEF50, FEF75, FEF2575, FEF7585, FET, Vext, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC, FIF25, FIF50, FIF75, R50, MVVcal, PIF, IRV, VC, EVC, IVC, IC, ERV, IRV, FEV1/VC, TV, VE, RR, ti, te, ti/t-tot, tv/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>	18-300 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%), T5
<b>Memory capacity</b>	about 500 hours of oximetry

<b>Certificates and registrations</b>	
<b>CE 0476</b>	MDR 2017/745
<b>FDA 510 (k)</b>	K 052140
<b>Health Canada</b>	71191 (Class II)
<b>EMDN liv.4</b>	Z121501
<b>CND Code</b>	Z12150102
<b>GMDN Code</b>	46906 (spiral), 45607 (spiro + oxy)
<b>Ministry of Health</b>	2494321/R (code 9110801I) 2494344/R (code 9110811I) 2494441/R (code 9110801O) 2494453/R (code 9110811O)
<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 IEC 62311:2019 EN 62311:2020

## 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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