

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

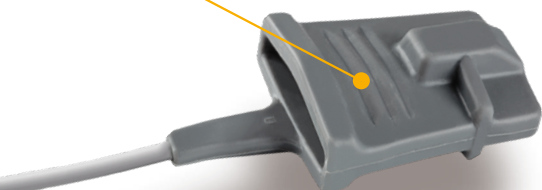
Oximetry sensor to detect blood oxygen saturation

Connection to external Postscript Printer

Integrated thermal printer

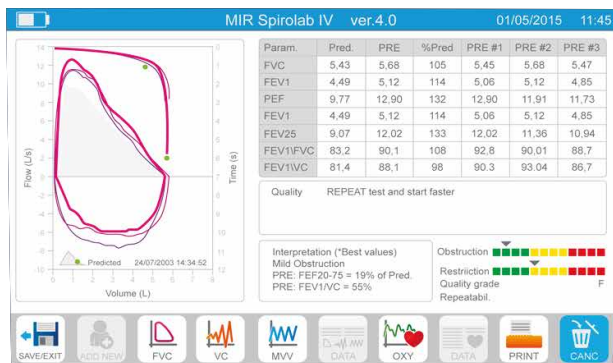
Customizable print and detailed immediate test reports. 80<120 prints with a single roll*.

(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
Single patient reusable turbine		Required, not included	Required	Required	Pack of 1 unit	Recommended by ATS



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	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)
Oximetry (optional)	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"> · For reusable and disposable miniflowmeter turbines (code 910595) · For spirolab code 911081 only Reusable soft adult sensor for oximetry test (code 919024)
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
Spirometry	
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)

Available tests	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	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
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	18-300 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%), T5
Memory capacity	about 500 hours of oximetry

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