Technical specification

Width	220 mm
Length	210 mm
Thickness	51 mm
Weight	1450 g (battery pack included)

Sensors

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

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

Power supply	Rechargeable battery and mains power Ni-MH, 6 elements
Current capacity	4500 mAh
Consumption	average 250 mA
Backup battery voltage	none
Batteries charger	Output voltage=12 V, current=1A, compliant with EN 60601-1
Autonomy	~10 hours
Connectivity	USB 2.0, Bluetooth® 2.1
Display	7 inch colour touch screen LCD Display with 800x480 resolution
Keyboard	absent, touchscreen
Mouthpieces	Ø 30 mm (1.18 inch)
Type of electrical protection	Internally powered Class II while charging battery
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage conditions	Temperature: MIN -40 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 95%RH
Transport conditions	Temperature: MIN -40 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 95%RH
Operating conditions	Temperature: MIN + 10 °C, MAX + 40 °C Humidity: MIN 10% RH, MAX 95%RH
Applied norms	Electrical Safety EN 60601-1 Electro Magnetic Compatibility EN 60601-1-2
Degree of protection against water penetration	IPX1 appliance protected against water leaks

Codes and equipments

911080E0	spiro
911080E1	spiro with reusable turbine
911080E2	spiro with 120 FlowMir
911081E0	spiro+oxy
911081E1	spiro+oxy with reusable turbine
911081E2	spiro+oxy with 120 FlowMir

Spirometry

Flow sensor	bi-directional digital turbine
Volume rate	10 L
Flow range	±16L/s
Volume accuracy	±2.5% or 50 mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)
Test available	FVC, VC, IVC, MVV, PRE-POST
Measured parameters	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)

Measurement method	Red and infrared absorption
SpO2 range	0-99%
SpO2 accuracy	± 2% between 70-99% SpO2
Average number of heart beats for the %SpO2 calculation	8 beats
Pulse Rate range	18-300 BPM
Pulse Rate accuracy	± 2BPM or 2% whichever is greater
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Test available	spot
Measured parameters	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
Memory capacity	about 500 hours oximetry

Certificates & Registrations

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

MIR

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

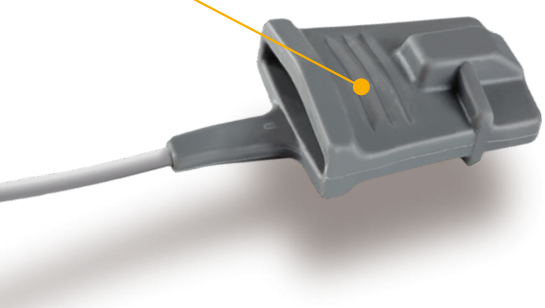
Connection to external Postscript Printer

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)

Calibration
Available on device, with calibration report printable by the instrument

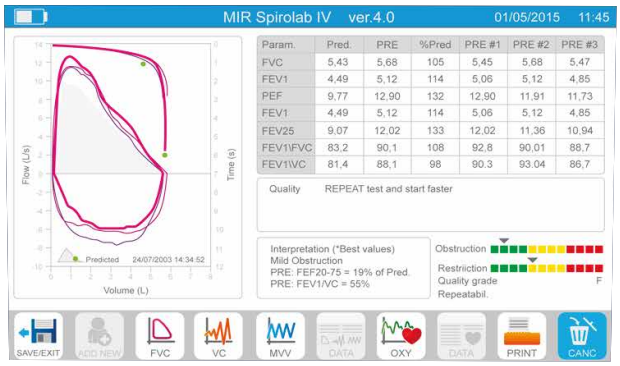
7” colour touchscreen
Intuitive interface and clear data display

SpO2% Sensor
Oximetry sensor to detect blood oxygen saturation



*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

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)

Pediatric incentive

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.

*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	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	·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 911080I1) 2494344/R (code 911081I1) 2494441/R (code 911080I0) 2494453/R (code 911081I0)
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

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