



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

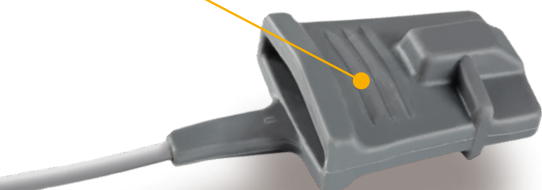
Oximetry sensor to detect blood oxygen saturation

Connection to external Postscript Printer

Integrated thermal printer

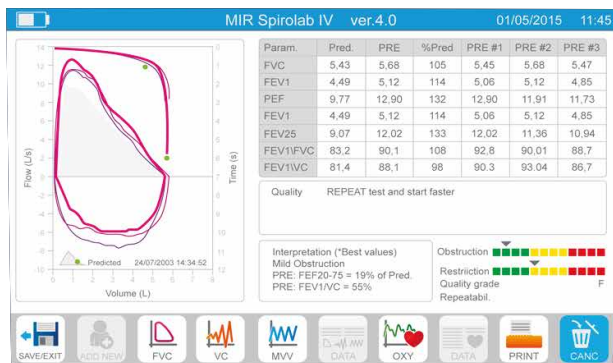
Customizable print and detailed immediate test reports. 80<120 prints with a single roll*.

(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 |

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

| | 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

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