

# SPIROLAB SPIROMETER: 7" TOUCHSCREEN AND SPO<sub>2</sub> OPTION



Health Canada



Dimensions: 220x210x51 mm  
(8,66x8,26x2")  
Weight: 1450 g (3,1lb)  
(battery pack included)



Miniflowmeter for reusable and disposable turbine (Ø 30 mm)

7" TOUCHSCREEN DISPLAY

PEDIATRIC INCENTIVE SYSTEM

DATABASE FOR 10,000 TESTS

USB 2.0, BLUETOOTH

33519

- 33519 SPIROLAB® SPIROMETER WITH 7" TOUCHSCREEN
  - 33520 SPIROLAB® SPIROMETER WITH 7" TOUCHSCREEN AND SpO<sub>2</sub>
- Fast, simple, durable diagnostic spirometer with Miniflowmeter.

## Features

- FVC, VC, MVV, PRE/POST Bronchodilator comparison with a wide range of selectable parameters
- long life rechargeable battery
- colour Touchscreen 7" display
- direct connection to external USB Printer PostScript
- 10,000 Spirometry tests or 500 hours of oximetry recording
- fast and silent built-in B/W printer with customizable printout format

- selectable internal software languages: GB, FR, IT, ES, DE, PT
- Oximetry option (only 33520)**

Adult (standard) and pediatric (optional) reusable finger probe available.

## Fast and user friendly

Each function can be activated by a simple touch.

## FlowMIR® disposable turbine

- complies with ATS/ERS standard

Totally disposable (mouthpiece, turbine) guarantees 100% hygiene, no cross contamination.

No calibration required.

MDR certified



Each turbine is factory calibrated with a computerized system and is individually packed in a clean room

33507

## Suitable for children

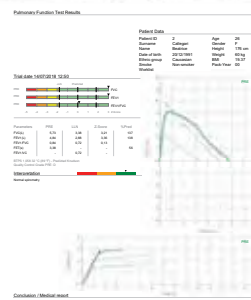
Patented pediatric incentive directly on the screen.  
No need of adaptor.

## MIR Spiro Basic PC software

High performances PC software for spirometry. See page 320.

Multilingual software:

GB, FR, IT, ES, DE, PT, PL, HU, RO, NL, LV, SE, CZ, RU, TR, JP, CN.



Printout: spirometry report

## STANDARD ACCESSORIES

- Battery charger
- 1 roll thermal paper
- Reusable turbine
- Carrying case

MIR Spiro basic PC software  
USB port and cable  
SpO<sub>2</sub> adult sensor (33520 only)  
Manual: GB, IT, FR, ES, DE, PT available on [www.gimaitaly.com](http://www.gimaitaly.com)



## TECHNICAL SPECIFICATIONS - SPIROMETRY

Power supply:	Rechargeable battery, approx. 10 hours autonomy
Battery charger:	100-240 V, 50-60 Hz, 400-200 mA
Temperature sensor:	semiconductor (0-45°C)
Flow sensor:	bi-directional digital turbine
Flow range:	±16L/s ±5% or 200mL/s
Volume accuracy:	±2.5% or 50mL
Dynamic resistance:	<0.5 cm H <sub>2</sub> O/L/s
Connectivity:	USB 2.0, Bluetooth®
Display:	7" colour touch screen LCD, 800x480 resolution
Mouthpieces:	Ø 30 mm (1.18 inch)
Electrical protection:	Class II
Norms:	Electrical safety standard EN 60601-1 Electromagnetic compatibility EN 60601-1-2

## SPIROMETRY PARAMETERS

FVC, FEV1, FEV1/FVC, PEF, FEF25, FEF50, FEF75, FEF25-75, FEF75-85, Lung Age, Extrapolated Volume, FET, Time to PEF, FEV0.5, 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).

## MIR SPIRO BASIC SOFTWARE REQUIREMENTS

Windows 7 (32/64 bit), 8 (32/64 bit), 10 (32/64 bit), 11 (32/64 bit).  
iOS operating system 10.13. See page 320 for details.

GIMA code	MIR code	ACCESSORIES AND SPARES	Minimum order
33695	-	SpO <sub>2</sub> probe - adult - spare	
33696	-	SpO <sub>2</sub> probe - paediatric - optional	
33697	910595	Miniflowmeter with cable - spare	
33410	-	Adult mouthpiece - Ø 30 mm ext	box of 500
33493	-	Thermal paper - 112 mm x 25 m	box of 10
33525	-	Antibacterial filter - disposable	box of 50
33507	910004	Disposable turbine with integrated mouthpiece	box of 60

## TECHNICAL SPECIFICATIONS - OXIMETRY (33520 only)

SpO <sub>2</sub> range:	0-99%
SpO <sub>2</sub> accuracy:	± 2% between 70-99% SpO <sub>2</sub>
Pulse Rate range:	18-300 BPM
Pulse Rate accuracy:	± 2 BPM or 2% whichever is greater
Memory capacity:	up to 500 hours oximetry

## OXIMETRY PARAMETERS (33520 only)

%SpO<sub>2</sub> and Pulse Rate (Min, Max, Average), Test duration, Total SpO<sub>2</sub> Events, T90% (SpO<sub>2</sub> time ≤89%), T89% (SpO<sub>2</sub> time ≤88%), T40 (Bradycardia duration with Pulse Rate <40 BPM), T120 (Tachycardia duration with Pulse Rate >120 BPM)



## 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 (Ø 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 H <sub>2</sub> O/L/s
Temperature sensor	semiconductor (0-45°C)
Test available	FVC, VC, IVC, MVV, PRE-POST 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
Measured parameters	Up to 10000 tests
Memory capacity	

## Oximetry (on request)

Measurement method	Red and infrared absorption
SpO <sub>2</sub> range	0-99%
SpO <sub>2</sub> accuracy	± 2% between 70-99% SpO <sub>2</sub>
Average number of heart beats for the %SpO <sub>2</sub> 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	SpO <sub>2</sub> % min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO <sub>2</sub> ≤ 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)





# 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

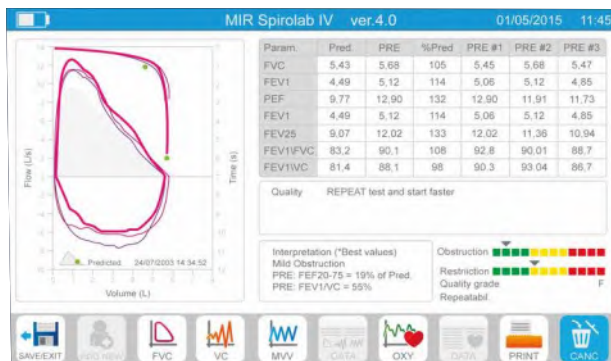
Customizable print and detailed immediate test reports.  
80<120 prints with a single roll\*.

(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

	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



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