

MIR Spirolab datasheet

cod. 911080x (spiro) cod. 911081x (spiro+oxy)



Technical specification

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

Sensors



mini-flowmeter (code 900595)
for reusable and disposable turbine dimension
($\varnothing$ 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® 5
Display	7 inch colour touch screen LCD Display with 800x480 resolution
Keyboard	absent, touchscreen
Mouthpieces	$\varnothing$ 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 +75 °C
	Humidity:	MIN 10% RH; MAX 95%RH
Transport conditions	Temperature:	MIN -40 °C, MAX +75 °C
	Humidity:	MIN 10% RH; MAX 95%RH
Operating conditions	Temperature:	MIN + 0 °C, MAX + 40 °C
	Humidity:	MIN 15% RH, MAX 95%RH
Degree of protection against water penetration	IPX1 appliance protected against water leaks	

Spirometry

Flow sensor	bi-directional digital turbine
Volume rate	10 L
Flow range	± 16 L/s

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Volume accuracy	±2.5% or 50 mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H ₂ O/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/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, V _{ext} , 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, t _i , t _e , t _i /t _{tot} , TV/t _i , MVV
Memory capacity	Up to 20000 tests

Oximetry (on request)

Measurement method	Red and infrared absorption
SpO₂ range	0-99%
SpO₂ accuracy	± 2% between 70-99% SpO ₂
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	SpO ₂ % min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO ₂ ≤ 90% (T90%, T89%), T5
Memory capacity	about 500 hours oximetry

Certificates & Registrations

CE 0476	MDR 2017/745
FDA 510 (k)	K 052140
Health Canada	71191 (class II)
EMDN liv.4	Z121501
CND code	Z12150102 (spiro) Z1203020408 (spiro + oxy)
GMDN code	46906 (spiro), 45607 (spiro + oxy)
Ministry of Health	2572528 /R (cod. 911080T) 2620983 /R (cod. 911081T) 2629696 /R (cod. 911080) 2629708 /R (cod. 911081)

Applied standard	Electrical Safety IEC 60601-1:2005 + A1:2012 + A2:2020 Electro Magnetic Compatibility IEC 60601-1-2:2014 + A1:2020 ISO 80601-2-61:2017 ISO 26782: 2009 ISO 23747: 2015 ATS/ERS:2005, 2019(update) IEC 60601-1-6:2010 + A1:2013 + A2:2020 IEC 60601-1-8:2006+ A1:2012 IEC 60601-1-9:2007+A1:2013 IEC 62304:2006 + A1:2015 ISO 10993-1:2018 Direttiva 2014/53/UE RED IEC 62311:2019
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