

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



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® 5
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 +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	±16L/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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