

MIR Spirodoc datasheet

code 910600x (spirometer) – code 910606 (oximeter) – code 910610x (spirometer + oximeter)



Technical specification

Main body		Accelerometer	Tri-axial accelerometer
Width	48 mm	Power supply	Rechargeable Lithium-Ion 3.7V, 1100 mAh
Length	101 mm	Current capacity	1100 mAh
Thickness	16 mm	Consumption	~20-30 mA (during test)
Weight	99 g (battery pack included)	Batteries charger	voltage=5 V DC, current=minimum 500 mA, Connector: micro USB type B compliant with EN 60601-1
Turbine housing			
Width	47 mm		
Length	46 mm		
Thickness	24 mm		
Weight	17 g		
Turbine		Autonomy	50 hours
	Reusable turbine (code 910002)	Connectivity	USB 2.0, Bluetooth® 2.1
	Disposable turbine (code 910004)	Display	LCD monochrome, 160×80 pixels Dimension 2.8 inch touchscreen
		Keyboard	Ø 30 mm (1.18 inch)
		Mouthpieces	Internally powered
		Type of electrical protection	
		Safety level for shock hazard	Type BF Apparatus

Spirometry

Flow sensor	bi-directional digital turbine
Flow range	±16L/s
Volume accuracy	±2.5% or 50mL
Flow accuracy	±5% or 200mL/s
Dynamic resistance	<0.5 cmH ₂ O/L/s
Temperature sensor	semiconductor (0-45°C)
Measured parameters	FVC, FEV1, FEV1/FVC%, PEF, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, FEF25, FEF50, FEF75, FEF2575, FET, EVol, ELA, FIVC, FIV1, FIV1/FIVC%, PIF, VC, IVC, EVC, IC, ERV, FEV1/VC%, TV, VE, RR, t _i , t _E , t _i /t _{Tot} , VT/t _i , 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	30-254 BPM
Pulse Rate accuracy	± 2BPM or 2%
Average interval for the calculation of cardiac pulse	8 seconds
Signal quality indication	0 - 8 segments on display
Measured parameters	
All test	%SpO2MIN, %SpO2MEAN, %SpO2MAX, BPM MIN, BPMMEAN, BPM MAX, Ttotal, Tanalysis, T<90%, T<89%, T<88%, T<87%, Ev%SpO2<89, ΔIndex, T<40BPM, T>120BPM, Ev<40BPM, Ev>120BPM
Sleep test	%SpO2BASE, BPMBASE, ODI, Mean Dur. Desat., TotDesaturat., Longest Desat., Desatur. Peak, BPM Index, Mean Desaturat., Mean Drop, Max Drop, BPM Variation, NOD4%, NOD89%, NOD90%, t.NOD4%, t.NOD89%, t.NOD90% Body position registration

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MAX 95%R	6MWT test	%SPO2 start, %SPO2 end, BPM start, BPM end, %SPO2 base, Tbaseline, Twalking, Trecovery, Distance, T2%ΔSPO2, T4%ΔSPO2, Predicted, %Predicted, Predicted min, %Predicted min AUC/Distance, Dyspnea, Dyspnea base, Dyspnea end, Dyspnea CHG, Fatigue base, Fatigue end, Fatigue CHG, Diastolic base, diastolic end, Systolic base, Systolic end, Steps, VMU, O2-GAP, O2
	Memory capacity	up to 300 hours oximetry

Applied norms

IEC 60601-1:2005 + A1:2012 + A2:2020
IEC 60601-1-2:2014 + A1:2020
IEC 60601-1-6:2010 + A1:2013 + A2:2020
IEC 60601-1-8:2007/A1:2012
IEC 60601-1-9:2007 + A1:2013
ISO 80601-2-61:2017
IEC 62304:2006 + A1:2015
IEC 62366-1:2015 + A1:2020
ISO 15223-1:2021
ISO 14971:2019
ATS/ERS Guidelines: 2005, update 2019
ISO 26782: 2009
ISO 23747: 2015
EN ISO 14971: 2019
ISO 10993-1: 2018
ISO 10993-5:2009
ISO 10993-10:2021
ISO 10993-23:2021
2011/65/UE Directive
EN ISO 15223-1:2021
ISO 20417:2021
ISO 2248:1985
ISO 23747:2015
EN ISO 26782:2009
Directive 2014-53-EU-RED
ETSI EN 300 328 V. 2.2.2:2019
ETSI 301 489-1 V. 2.1.1:2017
ETSI 301 489-17 V. 3.2.4:2020

Certificates & Registrations

CE 0476	MDR 2017/745
FDA 510 (k)	K 103530
Health Canada	71191 (class II), 75535 (class III)
EMDN liv.4	Z121501
CND code	Z12150102 (spiro) Z12150102 (spiro + oxy) Z1203020408 (oxy)
GMDN code	46906 (spiro), 45607 (oxy)
Ministry of Health	2493989/R (910600) 2494292/R (910606) 2494301/R (910610) 2621385/R (910600T) 2621372/R (910610T)