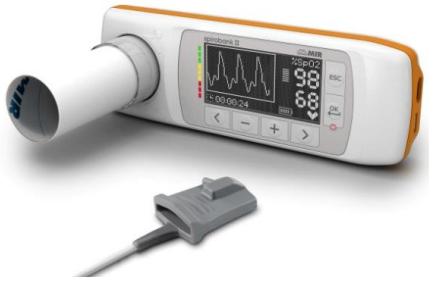
MEDICAL INTERNATIONAL RESEARCH

MIR Spirobank II Smart datasheet
code 911028x (spirometer) – code 911029x (spirometer + oximeter)



Technical specification

Width	55 mm
Length	160 mm
Thickness	25 mm
Weight	140 g (battery pack included)

Turbina

Reusable turbine (cod. 910002)

Disposable turbine (cod. 910004)

Power supply	Rechargeable Lithium-Ion 3.7V, 1100 mAh battery
Current capacity	1100 mAh
Consumption	~20-30 mA (during test)
Batteries charger	voltage=5 V DC, current=minimum 500 mA, Connector: micro USB B-type compliant with EN 60601-1
autonomy	50 hours
Connectivity	USB 2.0, Bluetooth® 4.0
Display	LCD monochrome, 160 × 80 pixel
Keyboard	membrane keyboard with 6 keys
Mouthpieces	Ø 30 mm (1.18 inch)
Type of electrical protection	Internal power supply
Safety level for shock hazard	Type BF Apparatus
IP protection level	IPX1
Conditions of use	Apparatus for continuous use
Storage and transport Conditions	Temperature: MIN -20 °C, MAX + 60 °C Humidity: MIN 10% RH; MAX 95%RH
Operating Conditions	Temperature: MIN + 10 °C, MAX + 40 °C Humidity: MIN 10% RH, MAX 95%RH

Spirometry

Flow sensor	bi-directional digital turbine
Flow range	±16L/s
Volume accuracy	±2.5% or 50 mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)
Test available	FVC, VC, IVC, MVV, PRE-POST

Measured parameters	FVC, FEV1, FEV1/FVC%, TPEF, FEV 0.5, FEV0.5/FVC%, FEV0.75, FEV0.75/FVC%, FEV2, FEV2/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25, FEF50, FEF75, FEF25-75, FEF75-85%, FET, Vext, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC%, FIF25, FIF50, FIF75, R50, PIF, IRV, VC, IVC, EVC, IC, ERV, FEV1/VC%, TV, VE, RR, t_I, t_E, t_I/t_{tot}, TV/t_I, MVV, MVV cal
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	30-300 BPM
Accuracy	± 2BPM or 2% whichever is greater
Averaging interval for	8 seconds average
Signal quality indication	0 - 8 segments on display
Test available	spot
Measured parameters	SpO2% min, max, average BPM min, max, average Test duration % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%, T89%)
Memory capacity	up to 300 hours oximetry

Certificati e registrazioni

CE 0476	MDR 2017/745
FDA 510 (k)	K 061712
Health Canada	71191 (class II), 75535 (class III)
EMDN liv.4	Z121501
CND code	Z12150102 (spiro) Z1203020408 (spiro + oxi)
GMDN code	46906 (spiro), 45607 (spiro + oxi)
Ministry of Health	2629714 /R (911028) 2564394 /R (911028T) 2629718 /R (911029) 2621340 /R (911029T)
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 ISO 10993-1:2018 EN ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-23:2021 ISO 20417:2021 ATS/ERS 2005, 2019 update ISO 23747:2015 EN ISO 26782:2009 ETSI EN 300 328 V. 2.2.2:2019 ETSI 301 489-1 V. 2.1.1:2017