

TECHNICAL datasheet

PRODUCT CODES - Spirodoc Configurations

910600E0 – Spirometer • 910600E1 – Spirometer with reusable turbine

910610E0 – Spirometer + Oximeter • 910610E1 – Spirometer + Oximeter with reusable turbine

Technical specification

Main body	
Width	48 mm
Length	101 mm
Thickness	16 mm
Weight	99 g (battery pack included)
Turbine housing	
Width	47 mm
Length	46 mm
Thickness	24 mm
Weight	17 g
Turbine	
	Reusable turbine (code 910002)
	Disposable turbine (code 910004)
Current capacity	Tri-axial accelerometer
Consumption	Rechargeable Lithium-Ion 3.7V, 1100 mAh
Batteries charger	1100 mAh
	~20-30 mA (during test)
	voltage=5 V DC,
	current=minimum 500 mA,
	Connector : micro USB type B
	compliant with EN 60601-1
Autonomy	50 hours
Connectivity	USB 2.0, Bluetooth® 2.1
Display	LCD monochrome, 160x80 pixels
	Dimension 2.8 inch
Keyboard	touchscreen
Mouthpieces	Ø 30 mm (1.18 inch)
Type of electrical protection	Internally powered
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage/shipping 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
Applied norms	IEC 60601-1:2005 + A1:2012
	EN 60601-1-2:2015
	ISO 80601-2-61:2017
	ISO 26782:2009
	ISO 23747:2015
	ATS/ERS: 2005, 2019 Update

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, EVC, IVC, 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	%SpO _{2MIN} , %SpO _{2MEAN} , %SpO _{2MAX} , BPM _{MIN} , BPM _{MEAN} , BPM _{MAX} , Ttotal, Tanalysis, T<90%, T<89%, T<88%, T<87%, Ev%SpO ₂ <89, ΔIndex, T<40BPM, T>120BPM, Ev<40BPM, Ev>120BPM
Sleep test	%SpO _{2BASE} , BPM _{BASE} , 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%
6MWT test	%SP02, BPM, Tbaseline, Twalking, Trecovey, Distance, T2%ΔSP02, T4%ΔSP02, Predicted, %Predicted, AUC/Distance, Dyspnea, Dyspnea, Fatigue, Diastolic, Systolic, Steps, VMU, O2-GAP, O2
Memory capacity	up to 300 hours oximetry
Certificates & Registrations	
CE 0476	MED 9826
FDA 510 (k)	K 103530
Health Canada	71191 (class II), 75535 (class III)
CND code	Z12150102 (spiro)
	Z1203020408 (spiro + oxy)
GMDN code	46906 (spiro), 45607 (spiro + oxy)
Ministry of Health	499389/R (910600), 501050/R (910606), 501619/R (910610), 1271090/R (910600I), 1271086/R (910606I), 1271078/R (910610I)

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