





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)
Accelerometer	tri axial accelerometer
Power supply	Rechargeable Lithium-Ion 3.7V, 1100 mAh
Current capacity	1100 mAh
Consumption	~20-30 mA (during test)
Backup battery voltage	none
Batteries charger	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, 160 × 80 pixel Dimension 2.8 inch
Keyboard	touchscreen
Mouthpieces	Ø 30 mm (1.18 inch)
Type of electrical protection	Class II device
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage 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	Electrical Safety Standard EN 60601-1 Electro Magnetic Compatibility EN 60601-1-2

Spirometry

Flow sensor	bi-directional digital turbine
Flow range	±16L/s
Volume accuracy	±3% or 50mL
Flow accuracy	±5% or 200mL/s
Dynamic resistance	<0.5 cmH2O/L/s
Temperature sensor	semiconductor (0-45°C)
Measured parameters	FVC, FEV1, FEV1/FVC%, FEV3, FEV3/FVC%, FEV6, FEV1/FEV6%, PEF, FEF25%, FEF50%, FEF75%, FEF25-75%, FET, Vext, Lung Age, FIVC, FIV1, FIV1/FIVC%, PIF, VC, IVC, IC, ERV, FEV1/VC%, VT, VE, Rf, ti, te, ti/t-tot, VT/ti, 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
Sleep test	Rapid Desaturation Analysis > 2,5 min. (ODI) Prolonged Desaturation Analysis < 5 min. (NOD) % Bradycardia Duration (<40 BPM) % Tachycardia Duration (>120 BPM) % of Time with SpO2 ≤ 90% (T90%, T89%, T88%, T87%) Body position recording during test Baseline, exercise, recovery with dyspnea and fatigue data entry. O2 GAP
6MWT test	
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 (910600I1) 1271086/R (910606I) 1271078/R (910610I1)