



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)

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 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
Temperature: MIN -20 °C,

Storage/shipping conditions

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, 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
SpO ₂ range	0-99%
SpO ₂ accuracy	± 2% between 70-99% SpO ₂
Average number of heart beats for the %SpO ₂ 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}, BPM_{MEAN}, BPM_{MAX}, T_{total}, T_{analysis}, T<90%, T<89%, T<88%, T<87%, Ev%SpO₂<89, ΔIndex, T<40BPM, T>120BPM, Ev<40BPM, Ev>120BPM

Sleep test

%SpO₂BASE, 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

%SPO₂, BPM, Tbaseline, Twalking, T_{recovery}, Distance, T2%ΔSPO₂, T4%ΔSPO₂, 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 (910600I1) 1271086/R (910606I) 1271078/R (910610I1)