



Applicable standards	ATS/ERS: 2005, 2019 Update ISO 26782: 2009 ISO 23747: 2015 ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223: 2016 IEC 60601-1: 2005+Amd1:2012 EN 60601-1-2: 2015 IEC 60601-1-6: 2010+Amd2013 EN 60601-1-11: 2015 ISO 80601-2-61: 2017
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Technical specification

Width	49 mm
Length	109 mm
Thickness	21 mm
Weight	60.7 g (batteries included)

Turbine



Reusable Turbine with plastic Mouthpiece (code 910013)



Disposable Turbine (code 910004)

Mouthpiece	Ø 30 mm (1.18 inches)
Power supply	2 batteries AAA 1.5 V
Consumption	max 12 mA average 8 µA (Stand by)
Autonomy	5-10 years
IP protection level	IP22
Connectivity	Bluetooth® 4.0
Type of electrical protection	Internally powered
Safety level for shock hazard	Type BF Apparatus
Conditions of use	Apparatus for continuous use
Storage conditions	Temperature: MIN -25 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 93% RH
Operating Conditions	Temperature: MIN + 5 °C, MAX + 40 °C Humidity: MIN 15% RH, MAX 93% RH
Shipping conditions	Temperature: MIN -25 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 93% RH

Spirometry

Flow sensor	bi-directional digital turbine
Flow range	16L/s (960 L/m)
Volume range	10 L
Volume accuracy	±2.5% o ±0.05L
Flow accuracy	±5.0% o 0,20 L/s
Dynamic resistance	<0.5 cm H ₂ O/L/s (a 12 L/s)
Temperature sensor	none
Available test	FVC
Measured parameters	FEV1, PEF, FVC, FEV1/FVC, FEV6, FEF2575
Additional parameters available with F/V version	FIVC, FIV1, PIF FEF25, FEF50, FEF75, EVol, FEV05, FEV075, FEV2, FEV3, FET, PEF Time
Memory capacity	the application on the remote device (smartphone/tablet) memorizes data

Oximetry

Measuring method	double wavelength
%SpO₂ range	70%-100%
%SpO₂ accuracy	±1.9%
Average number of beats for the %SpO₂ calculation	12 beats
Pulse Rate range	30-200 BPM
Pulse Rate accuracy	±3%
Average interval for Pulse rate calculation	12 seconds
Quality signal indicator	0-8 lines
Available tests	spot
Measured parameters	%SpO ₂ MIN, %SpO ₂ MEAN, %SpO ₂ MAX, BPM _{MIN} , BPM _{MEAN} , BPM _{MAX} , T _{TOTAL}
Wavelength sensors	Red 660 nm Infrared 880 nm
Maximum optical output power	1.2 mW

Certification & Registration

CE 0476	MED 9826
FDA 510 (k)	pending
Health Canada	pending
Codice CND	Z12150102
Codice GMDN	46906