



Applicable standards	ATS/ERS Guidelines: 2005 ISO 26782: 2009 ISO 23747: 2015 EN ISO 14971: 2012 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223:2016 IEC 60601-1:2005 + A1: 2012 EN 60601-1-2: 2015 EN 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 (code 910008)



Disposable Turbine (codice 910004)

Mouthpiece	Ø 30 mm (1.18 inches)
Power supply	2 batterie AAA 1.5 V
Consumption	max 12 mA medio 8 µA (Stand by)
Autonomy	circa 1000 test
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
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Shipping conditions	Temperature: MIN -25 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 93% RH
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Spirometry

Flow sensor	bi-directional digital turbine
Flow range	16L/s (960 L/m)
Volume range	10 L
Accuratezza del volume	±2.5% o ±0.05L
Accuratezza del flusso	±5.0% o 0,20 L/s
Resistenza dinamica	<0.5 cm H ₂ O/L/s (a 12 L/s)
Sensore di temperatura	none
Test disponibile	FVC
Parametri misurati	FEV1, PEF, FVC, FEV1/FVC ratio, FEV6, FEF2575
Capacità di memoria	the application on the smart phone memorizes data

Oximetry

Measuring method	double wavelength
Range %SpO₂	70%-100%
Accuracy %SpO₂	±1.9%
Average number of beats for the % SpO₂ calculation	12 beats
BP BPM range	30-200 BPM
BPM accuracy	±3%
Average interval for BPM calculation	12 seconds
Quality signal indicator	0-8 lines
Available tests	spot
Measured parameters	%SpO ₂ , BMP
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