



<b>Applicable standards</b>	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 IEC 60601-1-6:2010+Amd2013 IEC 60601-1-11: 2015 ISO 80601-2-61: 2017
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### Technical specification

<b>Width</b>	49 mm
<b>Length</b>	109 mm
<b>Thickness</b>	21 mm
<b>Weight</b>	60.7 g (batteries included)

#### Turbine



Single Patient Reusable Turbine with Mouthpiece (code 910013)



Disposable turbine (code 910004)

<b>Mouthpiece</b>	Ø 30 mm (1.18 inches)
<b>Power supply</b>	2 batteries AAA 1.5 V
<b>Consumption</b>	max 12 mA average 8 µA (Stand by)
<b>Autonomy</b>	5-10 years (Stand by)
<b>IP protection level</b>	IP22
<b>Connectivity</b>	Bluetooth® 4.0
<b>Type of electrical protection</b>	Internally powered
<b>Safety level for shock hazard</b>	Type BF Apparatus
<b>Conditions of use</b>	Apparatus for continuous use
<b>Storage conditions</b>	Temperature: MIN -40 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 95% RH
<b>Operating Conditions</b>	Temperature: MIN + 10 °C, MAX + 40 °C Humidity: MIN 10% RH, MAX 95% RH
<b>Shipping conditions</b>	Temperature: MIN -40 °C, MAX + 70 °C Humidity: MIN 10% RH; MAX 95% RH

### Spirometry

<b>Flow sensor</b>	bi-directional digital turbine
<b>Flow range</b>	16L/s (960 L/m)
<b>Volume range</b>	10 L
<b>Volume accuracy</b>	±3% or 0,1 L
<b>Flow accuracy</b>	±12% or 0,42 L/s
<b>Dynamic resistance</b>	<0.5 cm H2O/L/s (@ 12 L/s)
<b>Temperature sensor</b>	none
<b>Available test</b>	FVC
<b>Measured parameters</b>	FEV1, PEF, FVC, FEV1/FVC ratio, FEV6, FEF2575
<b>Memory capacity</b>	the application on the smart phone memorizes data

### Oximetry

<b>Measuring method</b>	double wavelength
<b>Range %SpO2</b>	70%-100%
<b>Accuracy %SpO2</b>	±1.9%
<b>Average number of beats for the calculation % SpO2</b>	12 beats
<b>BPM range</b>	30-200 BPM
<b>BPM accuracy</b>	±3%
<b>Average interval for BPM calculation</b>	12 seconds
<b>Quality signal indicator</b>	0-8 lines
<b>Available tests</b>	spot
<b>Measured parameters</b>	%SpO2, BMP
<b>Wavelength sensors</b>	red 660 nm Infrared 880nm
<b>Maximum optical output power</b>	1.2 mW

### Certification & registration

<b>CE 0476</b>	MED 9826
<b>FDA 510 (k)</b>	pending
<b>Health Canada</b>	pending
<b>CND Code</b>	Z12150102
<b>GMDN Code</b>	46906