



Applicable standards	IEC 60601-1:2005+Amd1:2012 EN 60601-1-2: 2015 EN ISO 14971: 2019 ISO 10993-1: 2018 2011/65/UE Directive EN ISO 15223:2016 IEC 60601-1-6:2010+Amd2013 IEC 60601-1-11: 2015 ATS/ERS Guidelines ISO 26782: 2009 ISO 23747: 2015
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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)

Power supply	2 batteries AAA 1.5 V
Consumption	max 12 mA Stand by 8 μ A medium

Backup battery voltage	none
Batteries charger	none
Autonomy	5-10 years (Stand by)
Connectivity	Bluetooth® 4.0
Mouthpieces	\varnothing 30 mm (1.18 inch)
Type of electrical protection	Internally powered
Safety level for shock hazard	Type BF Apparatus
IP protection level	IP22

Conditions of use Apparatus for continuous use

Storage conditions	Temperature: MIN -25 °C, MAX +70 °C Humidity: MIN 10% RH; MAX 93%RH
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Operating Conditions	Temperature: MIN +5 °C, MAX +40 °C Humidity: MIN 10% 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	\pm 16L/s
Volume accuracy	\pm 2.5% or 0,05 L
Flow accuracy	\pm 5.0% or 0,20 L/s
Dynamic resistance	<0.5 cm H ₂ O/L/s
Temperature sensor	none
Test available	FVC,
Measured parameters	FEV1, PEF, FVC, FEV1/FVC ratio, 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 smart phone memorizes data

Certificates & Registrations

CE 0476	MED 9826 by Kiwa-Cermet
FDA 510(k)	K072979
CND code	Z12150102
GMDN code	46906